

1 UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 IN RE: NATIONAL) MDL No. 2804
5 PRESCRIPTION OPIATE)
6 LITIGATION) Case No.
7) 1:17-MD-2804
8)
9 THIS DOCUMENT RELATES TO) Hon. Dan A.
10 ALL CASES) Polster
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Tuesday, May 14, 2019

HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
CONFIDENTIALITY REVIEW

Videotaped Deposition of JAMES E.
RAFALSKI, VOLUME 2, held at Weitz &
Luxenburg PC, 3011 West Grand Avenue, Suite
2150, Detroit, Michigan, commencing at
8:25 a.m., on the above date, before
Michael E. Miller, Fellow of the Academy of
Professional Reporters, Registered Diplomate
Reporter, Certified Realtime Reporter and
Notary Public.

GOLKOW LITIGATION SERVICES
877.370.3377 ph | fax 917.591.5672
deps@golkow.com

Page 412

1 A P P E A R A N C E S:
 2 MCHUGH FULLER LAW GROUP
 3 BY: MICHAEL J. FULLER, ESQUIRE
 4 mike@mchughfuller.com
 5 ALLAN "AJ" ELKINS, JR., ESQUIRE
 6 aj@mchughfuller.com
 7 AMY QUEZON, ESQUIRE
 8 amy@mchughfuller.com
 9 97 Elias Whiddon Road
 10 Hattiesburg, Mississippi 39402
 11 (601) 261-2220
 12 Counsel for MDL Plaintiffs

13 KELLER ROHRBACK LLP
 14 BY: GARY A. GOTTO, ESQUIRE
 15 ggotto@kellerrohrback.com
 16 3101 North Central Avenue
 17 Suite 1400
 18 Phoenix, Arizona 85012
 19 (602) 248-0088
 20 Counsel for MDL Plaintiffs

21 BRANSTETTER STRANCH & JENNINGS PLLC
 22 BY: TRICIA HERZFELD, ESQUIRE
 23 triciah@bsjfirm.com@bsjfirm.com
 24 223 Rosa L. Parks Boulevard
 25 Suite 200
 Nashville, Tennessee 37203
 (615) 254-8801
 Counsel for Tennessee Plaintiffs

REED SMITH LLP
 BY: ABIGAIL M. PIERCE, ESQUIRE
 abigail.pierce@reedsmith.com
 1717 Arch Street
 Suite 3100
 Philadelphia, Pennsylvania 19103
 (215) 851-8100
 Counsel for AmerisourceBergen Drug Corporation

Page 413

1 A P P E A R A N C E S:
 2 WILLIAMS & CONNOLLY LLP
 3 BY: STEVEN M. PYSER, ESQUIRE
 4 spyser@wc.com
 5 BRAD MASTERS, ESQUIRE
 6 bmasters@wc.com
 7 725 Twelfth Street, N.W.
 8 Washington, D.C. 20005
 9 (202) 434-5000
 10 Counsel for Cardinal Health Inc.

11 JONES DAY
 12 BY: NEAL J. STEPHENS, ESQUIRE
 13 nstephens@jonesday.com
 14 1755 Embarcadero Road
 15 Palo Alto, California 94303
 16 (650) 739-3939
 17 Counsel for Walmart Corporation

18 ROPES & GRAY LLP
 19 BY: ANDREW O'CONNOR, ESQUIRE
 20 andrew.o'connor@ropesgray.com
 21 WILLIAM DAVISON, ESQUIRE
 22 william.davison@ropesgray.com
 23 Prudential Tower
 24 800 Boylston Street
 25 Boston, Massachusetts 02199
 (617) 951-7000
 Counsel for Mallinckrodt Pharmaceuticals

COVINGTON & BURLING LLP
 BY: CHRISTOPHER K. EPPICH, ESQUIRE
 ceppich@cov.com
 1999 Avenue of the Stars
 Los Angeles, California 90067
 (424) 332-4800
 Counsel for McKesson Corporation

Page 414

1 A P P E A R A N C E S:
 2 COVINGTON & BURLING LLP
 3 BY: MEGHAN MONAGHAN, ESQUIRE
 4 mmonaghan@cov.com
 5 One City Center
 6 850 Tenth Street, N.W.
 7 Washington, D.C. 20001
 8 (202) 662-6000
 9 Counsel for McKesson Corporation

10 LOCKE LORD LLP
 11 BY: C. SCOTT JONES, ESQUIRE
 12 sjones@lockelord.com
 13 2200 Ross Avenue
 14 Suite 2800
 15 Dallas, Texas 75201
 16 (214) 740-8000
 17 Counsel for Henry Schein, Inc. and
 18 Henry Schein Medical Systems, Inc.

19 FOLEY & LARDNER LLP
 20 BY: JAMES W. MATTHEWS, ESQUIRE
 21 jmatthews@foley.com
 22 111 Huntington Avenue
 23 Boston, Massachusetts 02199
 24 (617) 342-4000
 25 Counsel for Anda Inc.

ARNOLD & PORTER KAYE SCHOLER LLP
 BY: DAVID D. FAUVRE, ESQUIRE
 david.fauvre@arnoldporter.com
 601 Massachusetts Avenue, N.W.
 Washington, D.C. 20001
 (202) 942-5000
 Counsel for Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc.

Page 415

1 A P P E A R A N C E S:
 2 KIRKLAND & ELLIS LLP
 3 BY: ERICA B. ZOLNER, ESQUIRE
 4 erica.zolner@kirkland.com
 5 KAITLYN L. COVERSTONE, ESQUIRE
 6 kaitlyn.coverstone@kirkland.com
 7 300 North LaSalle
 8 Chicago, Illinois 60654
 9 (312) 862-2000
 10 Counsel for Allergan Finance LLC

11 MORGAN LEWIS & BOCKIUS LLP
 12 BY: MAUREEN K. BARBER, ESQUIRE
 13 maureen.barber@morganlewis.com
 14 One Oxford Centre
 15 Thirty-Second Floor
 16 Pittsburgh, Pennsylvania 15219
 17 (412) 560-3300
 18 Counsel for Teva Pharmaceuticals USA Inc., Cephalon Inc., Watson Laboratories Inc., Actavis LLC, and Actavis Pharma Inc. f/k/a Watson Pharma Inc.

19 ZUCKERMAN SPAEDER LLP
 20 BY: GRAEME W. BUSH, ESQUIRE
 21 gbush@zuckerman.com
 22 PAUL B. HYNES, JR., ESQUIRE
 23 phynes@zuckerman.com
 24 (via teleconference)
 25 1800 M Street, N.W.
 Suite 1000
 Washington, D.C. 20036
 (202) 778-1800
 Counsel for CVS Indiana LLC and CVS Rx Services Inc.

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<p>1 APPEARANCES:</p> <p>2 DECHERT LLP</p> <p>3 BY: ERIK W. SNAPP, ESQUIRE</p> <p>4 erik.snapp@dechert.com</p> <p>5 35 West Wacker Drive</p> <p>6 Suite 3400</p> <p>7 Chicago, Illinois 60601</p> <p>8 (312) 646-5800</p> <p>9 Counsel for Purdue Pharma</p> <p>10 O'MELVENY & MYERS LLP</p> <p>11 BY: AMY R. LUCAS, ESQUIRE</p> <p>12 alucas@omm.com</p> <p>13 1999 Avenue of the Stars</p> <p>14 8th Floor</p> <p>15 Los Angeles, California 90067</p> <p>16 (213) 430-6000</p> <p>17 Counsel for Janssen Pharmaceuticals Inc.</p> <p>18 MARCUS & SHAPIRA LLP</p> <p>19 BY: JOSHUA A. KORBIN, ESQUIRE</p> <p>20 korbin@marcus-shapira.com</p> <p>21 One Oxford Centre</p> <p>22 35th Floor</p> <p>23 Pittsburgh, Pennsylvania 15219</p> <p>24 (412) 471-3490</p> <p>25 Counsel for HBC Services</p> <p>BARTLIT BECK HERMAN PALENCHAR & SCOTT LLP</p> <p>BY: KATHERINE M. SWIFT, ESQUIRE</p> <p>katherine.swift@bartlit-beck.com</p> <p>54 West Hubbard Street</p> <p>Suite 300</p> <p>Chicago, Illinois 60654</p> <p>(312) 494-4400</p> <p>Counsel for Walgreens Company</p>	<p>1 INDEX</p> <p>2</p> <p>3 APPEARANCES 412</p> <p>4 PROCEEDINGS 421</p> <p>5</p> <p>6 EXAMINATION OF JAMES E. RAFALSKI:</p> <p>7 BY MS. SWIFT 421</p> <p>8 BY MR. BUSH 562</p> <p>9 BY MR. O'CONNOR 630</p> <p>10 BY MS. LUCAS 703</p> <p>11 BY MS. ZOLNER 740</p> <p>12 BY MR. SNAPP 776</p> <p>13 BY MR. FAUVRE 794</p> <p>14 BY MS. BARBER 810</p> <p>15 BY MR. FULLER 829</p> <p>16 BY MR. MATTHEWS 838</p> <p>17</p> <p>18 CERTIFICATE 842</p> <p>19 ERRATA 845</p> <p>20 ACKNOWLEDGMENT OF DEPONENT 846</p> <p>21 LAWYER'S NOTES 847</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
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<p>1 APPEARANCES:</p> <p>2 BARNES & THORNBURG LLP</p> <p>3 BY: WILLIAM LEEDER, ESQUIRE</p> <p>4 bill.leeder@btlaw.com</p> <p>5 171 Monroe Avenue, N.W.</p> <p>6 Suite 1000</p> <p>7 Grand Rapids, Michigan 49503</p> <p>8 (616) 742-3930</p> <p>9 Counsel for H.D. Smith</p> <p>10 CAVITCH FAMLO & DURKIN CO. L.P.A.</p> <p>11 BY: ERIC J. WEISS, ESQUIRE</p> <p>12 eweiss@cavitch.com</p> <p>13 (via teleconference)</p> <p>14 1300 East 9th Street</p> <p>15 Cleveland, Ohio 44114</p> <p>16 (216) 621-7860</p> <p>17 Counsel for Discount Drug Mart</p> <p>18 FOX ROTHSCHILD LLP</p> <p>19 BY: STEPHAN A. CORNELL, ESQUIRE</p> <p>20 scornell@foxrothschild.com</p> <p>21 (via teleconference)</p> <p>22 2700 Kelly Road</p> <p>23 Suite 300</p> <p>24 Warrington, Pennsylvania 18976</p> <p>25 (215) 345-7500</p> <p>Counsel for Prescription Supply Inc.</p> <p>MORGAN LEWIS & BOCKIUS LLP</p> <p>BY: CAROLYN A. SILANE, ESQUIRE</p> <p>carolyn.silane@morganlewis.com</p> <p>(via teleconference)</p> <p>101 Park Avenue</p> <p>New York, New York 10178</p> <p>(212) 309-6000</p> <p>Counsel for Rite Aid</p> <p>VIDEOGRAPHER:</p> <p>David Lane,</p> <p>Golkow Litigation Services</p>	<p>1 DEPOSITION EXHIBITS</p> <p>2 JAMES E. RAFALSKI</p> <p>3 May 14, 2019</p> <p>4 NUMBER DESCRIPTION PAGE</p> <p>5 Rafalski-19 5/17/06 Corso Letter, 450</p> <p>6 WAGMDL00753477 -</p> <p>7 WAGMDL00753479</p> <p>8 Rafalski-20 Plaintiffs' Responses to 500</p> <p>9 the Amended and Clarified</p> <p>10 Discovery Ruling 12</p> <p>11 Supplemental</p> <p>12 Interrogatory Issued to</p> <p>13 Plaintiffs</p> <p>14 Rafalski-21 Excerpt from McCann 511</p> <p>15 Appendix 10</p> <p>16 Rafalski-22 E-mail(s), 519</p> <p>17 WAGFLDEA00000459 -</p> <p>18 WAGFLDEA00000460</p> <p>19 Rafalski-23 Rafalski Report 533</p> <p>20 Schedule II</p> <p>21 Rafalski-24 Excerpt from McCann 537</p> <p>22 Appendix 9</p> <p>23 Rafalski-25 Excerpt from McCann 546</p> <p>24 Appendix 11</p> <p>25 Rafalski-26 Consumer Value Stores IRR 609</p> <p>Report,</p> <p>CVS-MDLT1-000100763 -</p> <p>CVS-MDLT1-000100768</p> <p>Rafalski-27 Consumer Value Stores IRR 622</p> <p>Report,</p> <p>CVS-MDLT1-000100672 -</p> <p>CVS-MDLT1-000100757</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

<p style="text-align: right;">Page 420</p> <p>1 DEPOSITION EXHIBITS</p> <p>2</p> <p>3 Rafalski-28 Actavis SOM Logic 749</p> <p>4 Presentation,</p> <p>5 ALLERGAN_MDL_02181128 -</p> <p>6 ALLERGAN_MDL_02181172</p> <p>7 Rafalski-29 Plaintiff Cardinal Health 833</p> <p>8 Inc.'s Reply in Support</p> <p>9 of Motion for Preliminary</p> <p>10 Injunction</p> <p>11</p> <p>12 Rafalski-30 8/13/14 Rocque Letter to 835</p> <p>13 Hobart</p> <p>14 [MCKMDL Bates Obscured]</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 422</p> <p>1 is Kate Swift and I represent Walgreens,</p> <p>2 okay?</p> <p>3 A. Yes.</p> <p>4 Q. Did you have an opportunity to</p> <p>5 talk to the plaintiffs' lawyers after we</p> <p>6 finished yesterday?</p> <p>7 A. Yes, went to dinner together.</p> <p>8 Q. Did you talk about the</p> <p>9 substance of your testimony at all?</p> <p>10 A. No, ma'am.</p> <p>11 Q. What did you talk about with</p> <p>12 the lawyers last night at dinner?</p> <p>13 A. Just Detroit, the restaurant,</p> <p>14 general personal topics, children,</p> <p>15 activities, the weather.</p> <p>16 Q. You understand that the Court's</p> <p>17 rules require you to disclose all of your</p> <p>18 opinions in the report that you provided to</p> <p>19 us, correct, sir?</p> <p>20 A. Yes, sir -- or yes, ma'am. I'm</p> <p>21 sorry. Sorry.</p> <p>22 Q. The rules also require you to</p> <p>23 include the reasons supporting those opinions</p> <p>24 in your report.</p> <p>25 Do you understand that?</p>
<p style="text-align: right;">Page 421</p> <p>1 PROCEEDINGS</p> <p>2 (May 14, 2019 at 8:25 a.m.)</p> <p>3 THE VIDEOGRAPHER: We're now on</p> <p>4 the record. My name is David Lane,</p> <p>5 videographer for Golkow Litigation</p> <p>6 Services. Today's date is May 14th,</p> <p>7 2019. Our time is 8:25 a.m.</p> <p>8 This deposition is taking place</p> <p>9 in Detroit, Michigan in the matter of</p> <p>10 National Prescription Opiate</p> <p>11 Litigation. Our deponent today is</p> <p>12 James E. Rafalski. Counsel will be</p> <p>13 noted on the stenographic record.</p> <p>14 Our court reporter today is</p> <p>15 Mike Miller.</p> <p>16 Mr. Rafalski, I just want to</p> <p>17 remind you, you're still under oath</p> <p>18 from yesterday.</p> <p>19 THE WITNESS: Yes, sir, I</p> <p>20 understand. Thank you.</p> <p>21 EXAMINATION</p> <p>22 BY MS. SWIFT:</p> <p>23 Q. Good morning, Mr. Rafalski.</p> <p>24 A. Good morning.</p> <p>25 Q. We met a moment ago. My name</p>	<p style="text-align: right;">Page 423</p> <p>1 A. Yes.</p> <p>2 Q. That's so we can look at your</p> <p>3 report in advance of the deposition and then</p> <p>4 ask you questions about the opinions and what</p> <p>5 supports your opinions.</p> <p>6 Do you understand that?</p> <p>7 A. I understand.</p> <p>8 Q. If it's not in your report, we</p> <p>9 can't do any of that.</p> <p>10 Do you understand that?</p> <p>11 A. I understand that, yes, ma'am.</p> <p>12 Q. Are all of your opinions</p> <p>13 related to the defendants that you've -- you</p> <p>14 have opinions about included in your report?</p> <p>15 A. Yes, ma'am.</p> <p>16 Q. Are all of the bases for those</p> <p>17 opinions also included in your report?</p> <p>18 MR. FULLER: Form.</p> <p>19 A. Yes, ma'am.</p> <p>20 BY MS. SWIFT:</p> <p>21 Q. Do you understand what I mean</p> <p>22 when I say the bases for your opinions?</p> <p>23 MR. FULLER: Same objection.</p> <p>24 A. I'll accept an explanation if</p> <p>25 you want to give that to me.</p>

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1 BY MS. SWIFT:
2 Q. Are all of the reasons
3 supporting your opinions included in your
4 report?
5 A. Yes, ma'am.
6 MR. FULLER: Object to form.
7 BY MS. SWIFT:
8 Q. Throughout your report you
9 include footnotes citing documents and
10 testimony. It is fair to say that those
11 documents and testimony that you cite in the
12 footnotes provide the specific support for
13 whatever you've just said in the body of the
14 report?
15 MR. FULLER: Same objection.
16 A. Yes, I think that's an accurate
17 description of what -- the use of the
18 footnotes.
19 BY MS. SWIFT:
20 Q. If we wanted to figure out what
21 your basis or your reason was for a specific
22 point, we could look at what you've cited in
23 the footnote; is that fair?
24 MR. FULLER: Same objection.
25 A. I think that's a little

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1 restrictive. That rules out my experience
2 and my training, so there may be some other
3 factors that I include besides just the
4 footnote information.
5 BY MS. SWIFT:
6 Q. Setting aside your experience
7 and training, things you couldn't put in a
8 footnote --
9 A. Correct.
10 Q. -- is it fair to say that when
11 you include something in a footnote of your
12 report, that's the specific support for
13 whatever you've just said leading up to the
14 footnote?
15 A. Yes, ma'am. Generally the
16 footnote actually takes you to the document
17 or to the reference of where that statement
18 occurs.
19 Q. But the specific support is
20 referred to in the footnote. Then you have
21 to go look at the document. I understand
22 that. But the reference to whatever it is
23 that you are using to support the opinion is
24 found in the footnotes?
25 A. Yes, ma'am.

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1 MR. FULLER: I would just state
2 for the record that his report has
3 been compiled for an extended period
4 of time. There's been ongoing
5 discovery, still ongoing discovery and
6 productions. I think counsel is
7 correct, there has to be a basis
8 provided in the report, but he doesn't
9 have to provide all the examples.
10 BY MS. SWIFT:
11 Q. Sitting here today, you're not
12 planning to come to trial and offer different
13 support for your opinions than what you've
14 already provided in your report; is that
15 fair?
16 MR. FULLER: Object to form.
17 A. Other than I'm aware and I
18 think I state in the beginning of my report
19 that it's an ongoing discovery, so I think I
20 reserve the right to amend my report if any
21 supplemental documents would add or change my
22 opinion.
23 BY MS. SWIFT:
24 Q. And that's why I asked you
25 sitting here today, sir. I'll ask it again.

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1 Sitting here today, you're not
2 planning to come to trial and offer different
3 support for your opinions than what you've
4 offered in the report that's marked as
5 Exhibit 16, correct, sir?
6 A. Well, I want to answer that by
7 saying I currently don't know if there may be
8 a document that has been turned in after my
9 report, which was April 15th, up until today,
10 that may be necessary to be amended. So
11 there could be some documentation already.
12 As my report stands today, I
13 don't have any information that I know of
14 today that's been provided to me where I
15 would change or edit or provide a
16 supplemental to my report.
17 Q. So I believe that's a no,
18 right, sir?
19 A. I think it's a no but I think
20 I'm reserving in case there's something I
21 don't know about that -- up until today.
22 So I guess the question that
23 causes me some concern is that you tend -- I
24 tend to believe the question says that
25 this -- up to today, that I could not

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1 consider any information that may have been
 2 provided that is not in my report.
 3 Does that make sense?
 4 Q. It doesn't. I'm afraid it
 5 doesn't. I'm sorry, sir. Let me ask the
 6 question again.
 7 A. Okay.
 8 Q. Sitting here right now, as of
 9 this moment at 8:30 on Tuesday morning,
 10 May 14th, 2019, you're not aware of anything
 11 that is supportive of your opinions other
 12 than what you have cited in your report; is
 13 that fair?
 14 A. That's a correct statement, I
 15 would --
 16 MR. FULLER: Object to form.
 17 That is not the legal standard. He is
 18 only obligated to give you the basis
 19 of his opinion, not every example
 20 within his report.
 21 BY MS. SWIFT:
 22 Q. Sitting here today at 8:30 on
 23 May 14th, 2019, you're not aware of anything
 24 that is supportive of your opinions other
 25 than what you have cited in your report.

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1 Correct, sir?
 2 A. Yes, I would agree with that
 3 statement.
 4 Q. You have been instructed a
 5 number of times not to answer questions about
 6 your personal knowledge of investigations
 7 that were conducted while you were at the
 8 DEA.
 9 Do you recall that yesterday?
 10 A. Well, are you referring to the
 11 Touhy letter, the Touhy instruction from the
 12 government?
 13 Q. I'm specifically referring to
 14 the numerous times when your lawyer
 15 instructed you not to answer questions based
 16 on your personal knowledge of investigations
 17 or other things that you know about, only
 18 because of your work at the DEA.
 19 Do you recall that?
 20 A. Yes, that occurred yesterday.
 21 I recall that.
 22 Q. You're not going to come to
 23 trial and offer testimony based on any
 24 personal knowledge you've been instructed not
 25 to tell us about at the deposition, are you,

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1 sir?
 2 A. I think that's a legal issue.
 3 I would operate under the assumption that if
 4 I'm not allowed to talk to it today, that
 5 there's the possibility I wouldn't be able to
 6 talk to it at trial.
 7 But I don't know if there's
 8 some -- some kind of a legal issue there that
 9 would allow that, but that would be my
 10 understanding based on what I could say
 11 today.
 12 Q. So is it your position that if
 13 your lawyers asked you to offer testimony
 14 that you were instructed not to give at your
 15 deposition, then you would provide that
 16 testimony?
 17 A. I would probably say yes, I
 18 would offer that testimony.
 19 Q. When you were at the DEA, you
 20 sometimes requested reports from the DEA's
 21 ARCOS database as part of your diversion
 22 investigations, correct, sir?
 23 A. Yes, ma'am, that would be part
 24 of my role as a diversion investigator.
 25 Q. You might request an ARCOS

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1 analysis, just as an example, of oxycodone
 2 30-milligram products shipped to a particular
 3 pharmacy over a particular time period?
 4 A. You've described one of the
 5 potential scenarios where you could request
 6 information from ARCOS.
 7 Just for clarification, some of
 8 those I could run myself, so it wouldn't
 9 always require me to request it from DEA
 10 headquarters.
 11 Q. Did you do that from time to
 12 time?
 13 A. Yes, but only -- only if the
 14 number of transactions would be able to be
 15 displayed at -- on my computer within my
 16 system. So could I explain that a little
 17 further?
 18 Q. Sure.
 19 A. So there's some transactions
 20 where they're so voluminous that it's
 21 impossible for me to look at them. So, for
 22 example, the distribution you talk about, the
 23 transactions may be so high that to look at a
 24 month, I'd have to look at it a week at a
 25 time, or to look at six months, I'd have --

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1 so it would take numerous, numerous
 2 transactions.
 3 So there's two different ways.
 4 One way I just would look at it if it can be
 5 processed by my computer. If it's not, then
 6 I make the formal request to the ARCOS
 7 division, and then they either send it to me
 8 or they open a link where I can view it.
 9 It comes down to a computer, I
 10 think, hardware issue.
 11 Q. Understood.
 12 When you ran reports from the
 13 ARCOS database, did you typically look at a
 14 particular drug like oxy 30?
 15 MR. FULLER: And, Counsel, I'm
 16 assuming you're just asking generally.
 17 And I'll remind you of your Touhy
 18 obligation as well.
 19 MS. SWIFT: Yes, I'm asking
 20 generally. I'll ask it again.
 21 BY MS. SWIFT:
 22 Q. Generally, when you ran ARCOS
 23 reports, did you run them on a particular
 24 drug, like oxycodone 30 milligrams?
 25 A. Being able to run an ARCOS

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1 report, you could query any drug by any drug,
 2 by any date range, by numerous factors. Any
 3 information that's in an ARCOS report, I
 4 could query it by that data field. So yes.
 5 Q. Okay. Maybe my question wasn't
 6 clear.
 7 I'm asking you specifically
 8 when you would run your ARCOS reports, was it
 9 typical for you to focus on a particular
 10 drug? In other words --
 11 A. No.
 12 Q. -- when you ran your ARCOS
 13 reports, did you run a report to show all of
 14 the oxycodone and all of the hydrocodone
 15 together shipped to a particular pharmacy?
 16 A. A report could be run various
 17 different ways. I guess how I ran my report
 18 is dependent on what type of investigation I
 19 was conducting. So there was no set way that
 20 I would, you know, request reports. It would
 21 always be depending on what I planned to do
 22 with the investigation or what I was
 23 investigating and how I was going to utilize
 24 it would dictate on how I would run it.
 25 Q. Would an ARCOS analysis of

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1 oxycodone 30-milligram products shipped to a
 2 particular pharmacy over a particular period
 3 of time, either a week or a month or some
 4 other period, would that be a typical ARCOS
 5 report for you?
 6 MR. FULLER: Counsel, I let it
 7 go a little bit. I think you're
 8 encroaching on his Touhy
 9 authorization.
 10 THE WITNESS: I'm just
 11 considering what my counsel said. I'm
 12 processing whether that's something
 13 that would be readily available
 14 outside of the --
 15 MR. FULLER: So if it's not
 16 readily available --
 17 THE WITNESS: I would say that
 18 I can't answer that question based
 19 on --
 20 BY MS. SWIFT:
 21 Q. Do you recall testifying in a
 22 case involving H.D. Smith?
 23 A. I do.
 24 Q. Do you recall in that case you
 25 testified about an ARCOS report that you had

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1 requested involving oxycodone 30-milligram
 2 products shipped to a particular pharmacy
 3 over a two-year period?
 4 A. I did not run that report.
 5 Q. Did you request that report?
 6 A. No, ma'am.
 7 Q. You -- when you request an
 8 ARCOS analysis as a diversion investigator,
 9 are you looking to see whether there's a
 10 large volume increase in shipments of a
 11 particular drug to a particular pharmacy?
 12 MR. FULLER: Counsel --
 13 BY MS. SWIFT:
 14 Q. Just in general?
 15 MR. FULLER: -- that
 16 specifically goes to investigations
 17 conducted as an agent. It absolutely
 18 violates his Touhy obligation.
 19 MS. SWIFT: I'm not asking
 20 about any particular investigation.
 21 MR. FULLER: I didn't say you
 22 were, but it's an investigative
 23 process. Don't answer that. If she
 24 wants to know, she can ask the 30(b)
 25 designee from the DEA on Friday.

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1 BY MS. SWIFT:
2 Q. You testified yesterday that
3 you focused your investigations on particular
4 drug strengths as opposed to drug families.
5 Do you remember that testimony
6 from yesterday that your counsel allowed you
7 to provide?
8 A. Can you ask the question again?
9 Q. Sure.
10 A. This is not in regards to
11 ARCOS, this is just a general question?
12 Q. Nope, just a general question.
13 A. Okay.
14 Q. You testified yesterday you
15 would focus your investigations on particular
16 drug strengths as opposed to drug families.
17 Do you remember that testimony?
18 A. I remember the testimony. I'm
19 not sure that's exactly what I testified --
20 how I testified.
21 Q. I don't mean to say that I'm
22 giving it to you back verbatim, but just
23 generally, that's what you testified
24 yesterday?
25 A. Generally I would say it's as

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1 important to look at specific highly abused
2 drugs as it is to look at drugs in a group.
3 Q. You -- I believe yesterday you
4 mentioned drug strengths like oxycodone 30.
5 Do you remember that?
6 A. Yes, ma'am.
7 Q. Is oxycodone 30 more likely to
8 be diverted than lower strengths of
9 oxycodone?
10 A. Based on my experience as a
11 diversion investigator and the cases that I
12 worked, I would answer yes to that. But I
13 would also add, that would be kind of an
14 overall opinion. Sometimes there would be
15 other strengths of oxycodone that may be
16 abused in different geographic areas.
17 Q. Like oxycodone 80 perhaps?
18 A. Yes, or oxycodone 5 perhaps.
19 Q. Uh-huh. It's your testimony
20 that oxycodone 5 is typically diverted?
21 A. Not typically diverted, but I
22 have experience in certain geographic areas
23 where that is the more desirable drug to be
24 diverted.
25 Q. Is it your testimony that

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1 oxycodone 30 is more likely to be diverted
2 than oxycodone 5?
3 A. That would be my testimony
4 based on my experience in the cases I worked
5 on.
6 MR. FULLER: Object to form.
7 BY MS. SWIFT:
8 Q. Am I correct, circling back to
9 the ARCOS question just briefly, you can use
10 the ARCOS database to look at the particular
11 drug strength you're concerned about?
12 MR. FULLER: I would give you
13 the same Touhy reminder.
14 A. I'm not going to answer based
15 on the DEA's Touhy --
16 BY MS. SWIFT:
17 Q. Just so I understand, you can't
18 tell me sitting here today whether you can
19 use the DEA's ARCOS database to focus on a
20 particular drug strength?
21 MR. FULLER: How it's
22 particularly queried for investigative
23 purposes, no, he's not going to
24 answer.
25 MS. SWIFT: I want to get an

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1 answer from the witness on this
2 question, Mike, if you don't mind.
3 BY MS. SWIFT:
4 Q. Sitting here today, you can't
5 testify about whether you can use the DEA's
6 ARCOS database to query it for a particular
7 drug strength such as oxycodone 30; is that
8 correct?
9 A. What I'd like to say is my
10 understanding of the Touhy letter from the
11 government is that I can't testify to
12 anything that's not readily available as an
13 open source, and I don't believe that
14 particular answer to that particular question
15 would be something that would be readily
16 available, so on the advice of counsel, I'm
17 not going to answer that question.
18 Q. Would you give the same answer
19 to any other question about how queries can
20 be run on the DEA's ARCOS database? Would
21 you refuse to answer those questions?
22 A. I think that would depend on
23 the question. I know that there's some
24 summary information that the DEA posts on the
25 DEA website, and that's ARCOS data. So if

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1 there were questions related to the summary
2 data, I think I could answer any questions
3 related to that data because it's obviously
4 posted on the DEA website.
5 Q. All right. I'd like you to
6 turn to page 37 of your report, which I
7 believe you have in front of you.
8 A. It is.
9 Q. And I understand it's
10 Exhibit 16.
11 A. It is.
12 Q. Pages 37 through 40 of your
13 report are within a section that starts on
14 page 36.
15 Do you see that?
16 A. Yes, ma'am, titled Maintenance
17 of Effective Controls Against Diversion of
18 Controlled Substances.
19 Q. Yeah. And at the top of
20 page 37, just before the bullet list starts,
21 you wrote: Included below are some key
22 components that one would expect to see an
23 operational system designed to maintain
24 effective controls against diversion.
25 Did I read that correctly?

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1 A. You did, ma'am.
2 Q. Okay. Then following that
3 statement at the top of page 37 of your
4 report, you've included a list, a
5 bullet-pointed list, several levels of bullet
6 points, that carries all the way over to
7 page 40.
8 Would you agree with that?
9 A. Yes, ma'am.
10 Q. Is that list of bullet points
11 on pages 37 to 40, is it your opinion that
12 those are requirements to be included in a
13 distributor's suspicious order monitoring
14 system?
15 A. No, I wouldn't say they're
16 requirements. As the initial statement said,
17 they would -- I would expect to see those as
18 components of an operational system, but it's
19 not a -- not dictating or saying that they're
20 a requirement by the government.
21 Q. You're not saying that any of
22 those bullet points on pages 37 through 40
23 are requirements, not a single one of them?
24 A. Oh, to meet the maintenance of
25 effective controls, I think they're all

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1 requirements, but I understood your question
2 to say is this something that would be a
3 regulatory requirement, that something would
4 be in a regulation, these specific things.
5 Q. Let me --
6 A. Based on my experience, these
7 are all the things that I believe should be
8 present in a functioning operational
9 suspicious order system.
10 Q. Let me see if I understand your
11 testimony.
12 You're saying that the list of
13 components on pages 37 to 40 are not
14 requirements under the DEA's suspicious order
15 monitoring regulation; is that correct?
16 That's part one.
17 A. Well, the word "requirement" is
18 kind of the word that I'm thinking about. So
19 if you're trying to say that it's a mandate,
20 I would say in order for me to say that it's
21 an operational system, then these things
22 would need to be present. If they weren't
23 present, it wouldn't be an operational
24 system.
25 So if you were to say that you

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1 could take this and say the DEA said you must
2 have these things in your system, there's a
3 possibility that maybe one of them wouldn't
4 be there and it still could function.
5 So I wouldn't say -- I don't
6 want to say that this is dictating exactly
7 what has to be in a system, but in my
8 experience in reviewing a lot of systems,
9 these would be the key components I would
10 expect to see.
11 Q. All right. Now I'm more
12 confused than I was before.
13 A. Okay.
14 Q. If I understand what you're
15 saying, it seems like you're saying the
16 bullet list at pages 37 to 40 are not
17 required by the DEA's suspicious order
18 monitoring regulation, but they are required
19 by the maintenance of effective controls
20 against diversion?
21 A. Let me start over. So --
22 Q. Just -- can you just say yes or
23 no? I really want to just know if I'm
24 following you.
25 MR. FULLER: No, he can explain

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1 his answer. Go ahead.
2 MS. SWIFT: Before we go any
3 further on that point, my colleagues
4 were very, very patient yesterday. I
5 just want to remind counsel of Special
6 Master Cohen's ruling that we are
7 actually entitled to seek and obtain
8 yes-or-no answers where that's all we
9 really want. He put that on the
10 record in the Egilman deposition. I
11 can give you the citation at a break
12 if you'd like, Mike.
13 MR. FULLER: I don't need it.
14 BY MS. SWIFT:
15 Q. I would just right now -- we
16 can get to the explanation, but for right
17 now, to make sure I'm following you, I would
18 like to know if what you're trying to explain
19 is that the list on pages 37 to 40, that list
20 of components is not required by the DEA's
21 suspicious order monitoring regulation, but
22 that you think it is required under the
23 maintenance of effective controls against
24 diversion.
25 A. I don't believe that's what I

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1 said, and I'd like to correct that.
2 Q. Thank you. Please do.
3 A. Okay. So, first of all, the
4 maintenance of effective controls is the
5 large regulation which is above, or the
6 hierarchy, and then the next regulation would
7 be the suspicious order monitoring system.
8 Q. Can I stop you right there just
9 to make sure we're on the same page?
10 A. Yes.
11 Q. Is it 1301.74(a)?
12 A. Yes.
13 Q. Thank you.
14 MR. FULLER: I'm sorry. Is
15 what 13 --
16 MS. SWIFT: The larger --
17 THE WITNESS: Maintenance of
18 effective controls.
19 MR. FULLER: No. Is that CSA?
20 THE WITNESS: Well, the CSA
21 is -- I'm sorry.
22 MS. SWIFT: Counsel, did you
23 just correct the witness' testimony on
24 the record?
25 MR. FULLER: I was trying to

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1 clarify.
2 MS. SWIFT: All right. Let me
3 see if I can clean this up.
4 MR. FULLER: Sure.
5 BY MS. SWIFT:
6 Q. There was a pronoun in the
7 question that I thought Mike was correcting.
8 When you say -- let's see. The
9 maintenance of effective controls is in the
10 large regulation which is above, or the
11 hierarchy, did you mean 1301.74(a)?
12 A. Well, that is the regulation.
13 I'm also aware that the laws in 823, USC 823.
14 Q. As your counsel just reminded
15 you?
16 A. Well, I've always known that
17 whether counsel reminded me or not.
18 Q. Understood. Understood.
19 A. So that's the regulation, it's
20 both the law regulation and the law. Only --
21 1301.74(b) is only a regulation, which is
22 part of the security program, which is part
23 of maintenance of effective controls.
24 So it's kind of bulleted so
25 that the top regulation is maintenance of

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1 effective controls. Falling under that is
2 suspicious order system.
3 Q. So the list on 37 to 40, these
4 are not requirements under 1301.74(b), the
5 suspicious order monitoring regulation,
6 correct?
7 A. So I'd like to answer that by
8 saying I believe these are all components,
9 which would be necessary to have an effective
10 suspicious monitoring -- a suspicious order
11 monitoring system.
12 Q. And with respect, sir, that's
13 not what I asked you.
14 Are the bullet list components
15 on pages 37 to 40 of your report required
16 under 1301.74(b), the suspicious order
17 monitoring --
18 A. Yes, they are.
19 Q. Okay. All of them?
20 A. Yes.
21 Q. Okay. Great. Thanks.
22 Is it possible to have a
23 compliant suspicious order monitoring system
24 without all of these components?
25 A. Yes, I think it would be

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1 possible.
2 Q. But they are all requirements?
3 A. Based on -- depending on the
4 scope of the business that's the customer and
5 based on the scope of activity of the
6 distributor, I would say that some of
7 these -- there could be some of these that
8 would not be necessary. But I'd also say
9 that there may be some that aren't identified
10 on this list. And also, based on the fact
11 that the distribution activity is not static
12 and it changes.
13 Q. So if I'm following you, all of
14 the bullet-listed components on pages 37 to
15 40 are, in fact, required under 1301.74(b),
16 but you could have a compliant suspicious
17 order monitoring system without all of these
18 compliant -- components, and, in fact, there
19 may be other components that are required
20 under 1301.74(b) that are not included in
21 this list.
22 Do I have all that, correct,
23 sir?
24 A. I believe that's correct, yes.
25 Q. Okay.

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1 A. I'm not saying this is an
2 exclusive list and there might not be other
3 things that I have not considered or might
4 come up based on the type of business
5 activities that are involved.
6 Q. On page 39, if you would take a
7 look, please. You say, the top bullet, that:
8 A robust and well-documented due diligence
9 program is key.
10 And then it goes on from there
11 and provides components that you say you
12 would like to see in a due diligence
13 compliance program for suspicious orders,
14 correct, sir?
15 A. Yes, ma'am.
16 Q. Is it your opinion that a
17 distributor has to do all of the diligence
18 steps listed here in order to comply with the
19 law?
20 A. Yes, ma'am.
21 Q. All right. I want you to hold
22 on to these pages of your report for a
23 minute, please. And I'm going to hand you a
24 document. This will be Exhibit 19.
25 (Whereupon, Deposition Exhibit

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1 Rafalski-19, 5/17/06 Corso Letter,
2 WAGMDL00753477 - WAGMDL00753479, was
3 marked for identification.)
4 MR. FULLER: Are they all the
5 same?
6 MS. SWIFT: They're all the
7 same.
8 MR. FULLER: Okay.
9 BY MS. SWIFT:
10 Q. Okay. Exhibit 19 is a
11 May 17th, 2006 letter from the DEA to Todd
12 Polarolo at Walgreens in Perrysburg, Ohio,
13 correct, sir?
14 A. Yes.
15 Q. Do you recognize this as a
16 letter the DEA sent to Walgreens after an
17 audit of Walgreens' Perrysburg, Ohio
18 distribution center in 2006?
19 A. I recognize it only based on my
20 review of documents for preparation of this
21 is the first time I've seen this, from my
22 report.
23 Q. You're mentioned in the first
24 paragraph of the May 17th, 2006 letter,
25 correct, sir?

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1 A. I was there, yes, ma'am.
2 Q. When you were at the Detroit
3 field office, you were involved in this audit
4 of Walgreens' Perrysburg, Ohio distribution
5 center, correct, sir?
6 A. Yes, ma'am.
7 Q. This was a routine audit before
8 Walgreens' Perrysburg distribution center
9 started distributing Schedule II controlled
10 substances in early 2007, correct, sir?
11 A. No, that's not correct.
12 Q. What is the basis of your
13 statement that that's not correct?
14 A. It's a regulatory audit, but it
15 was just scheduled as part of the work plan
16 program. It wasn't in response to the second
17 part of your question, Schedule II controlled
18 substance authorization.
19 Q. Are you offering that testimony
20 based on your personal involvement with an
21 investigation of Walgreens while you were at
22 the DEA?
23 MR. FULLER: Again, I remind
24 you, Mr. Rafalski, that your
25 authorization does not and

<p style="text-align: right;">Page 452</p> <p>1 specifically addresses the fact that</p> <p>2 Walgreens was an investigation that</p> <p>3 you conducted that you're not</p> <p>4 authorized to talk about it based on</p> <p>5 your personal knowledge. Just from</p> <p>6 what information you gained in this</p> <p>7 litigation.</p> <p>8 BY MS. SWIFT:</p> <p>9 Q. Do you want to retract the</p> <p>10 testimony that you gave a moment ago?</p> <p>11 A. Yes, thank you.</p> <p>12 Q. This 2006 letter that I marked</p> <p>13 as Exhibit 19 that the DEA sent to Walgreens</p> <p>14 does not include the three pages of guidance</p> <p>15 on what Walgreens' suspicious order</p> <p>16 monitoring system should look like that you</p> <p>17 included in your report at pages 37 to 40,</p> <p>18 does it, sir?</p> <p>19 A. It does not.</p> <p>20 Q. This 2006 letter the DEA sent</p> <p>21 Walgreens, it says what DEA thought Walgreens</p> <p>22 was doing wrong. It doesn't provide an</p> <p>23 explanation of what we should do to do it</p> <p>24 right, correct, sir?</p> <p>25 A. That's an accurate description</p>	<p style="text-align: right;">Page 454</p> <p>1 would agree that I worked with them, but I</p> <p>2 was present at the registered location.</p> <p>3 Q. You worked with Steve Kneller a</p> <p>4 fair amount? He works at the Perrysburg</p> <p>5 distribution center.</p> <p>6 A. I know the name Mr. Kneller. I</p> <p>7 think it's K-N-E-L-L-E-R?</p> <p>8 Q. Correct.</p> <p>9 A. I recognize that he was the</p> <p>10 person that if I was on-site, that he would</p> <p>11 be the person that I would have contact with,</p> <p>12 yes, ma'am.</p> <p>13 Q. Did you know Justin Joseph as</p> <p>14 well?</p> <p>15 A. There was another -- there was</p> <p>16 one other person with him, and I don't know</p> <p>17 that that was Mr. Joseph. I do remember who</p> <p>18 Mr. Polarolo was, but I'm not sure.</p> <p>19 Q. You never told Steve or Justin</p> <p>20 or Todd Polarolo or anybody else at the</p> <p>21 Perrysburg distribution center, here's a list</p> <p>22 of things your suspicious order monitoring</p> <p>23 system is supposed to have, did you, sir?</p> <p>24 MR. FULLER: Object to form.</p> <p>25 I'd remind you of your Touhy</p>
<p style="text-align: right;">Page 453</p> <p>1 of what the letter says, yes, ma'am.</p> <p>2 Q. You did not provide to</p> <p>3 Walgreens the three pages of requirements</p> <p>4 that are included in your report. You didn't</p> <p>5 give those to Walgreens in 2006, correct,</p> <p>6 sir?</p> <p>7 MR. FULLER: Object to form.</p> <p>8 Don't answer that, that would be based</p> <p>9 on your own investigation, not</p> <p>10 knowledge of this case.</p> <p>11 BY MS. SWIFT:</p> <p>12 Q. You're not going to come to</p> <p>13 trial and say you provided these three pages</p> <p>14 of guidance to Walgreens in 2006, correct,</p> <p>15 sir?</p> <p>16 A. If the Touhy is still in place,</p> <p>17 I would say that I would not be able to</p> <p>18 testify to that.</p> <p>19 Q. You worked with the folks at</p> <p>20 Walgreens' Ohio distribution center for</p> <p>21 several years, correct, sir?</p> <p>22 A. I'll respond to that question</p> <p>23 by saying as part of my assignments as a</p> <p>24 diversion investigator, I went on-site to</p> <p>25 that facility several times. I'm not sure I</p>	<p style="text-align: right;">Page 455</p> <p>1 authorization.</p> <p>2 THE WITNESS: Based on the</p> <p>3 Touhy, I'm not going to answer.</p> <p>4 BY MS. SWIFT:</p> <p>5 Q. You don't say anything like</p> <p>6 that -- strike that.</p> <p>7 The DEA doesn't say anything</p> <p>8 like that in this 2006 letter, correct, sir?</p> <p>9 A. None of the things that are in</p> <p>10 the pages we've discussed is present in this</p> <p>11 letter.</p> <p>12 Q. You also don't say in your</p> <p>13 report that you told Walgreens at any point</p> <p>14 in time, here's what your suspicious order</p> <p>15 monitoring system is supposed to look like?</p> <p>16 A. My report does not indicate</p> <p>17 that I told them that, that's a correct</p> <p>18 statement.</p> <p>19 Q. Did anything prevent you from</p> <p>20 providing these pages of guidance on</p> <p>21 suspicious order monitoring to Walgreens in</p> <p>22 2006 or at any other point in time?</p> <p>23 MR. FULLER: Object to form.</p> <p>24 If it would deal with internal DEA</p> <p>25 policies and what agents were and were</p>

<p style="text-align: right;">Page 456</p> <p>1 not allowed to do, you're not 2 authorized to answer that. 3 THE WITNESS: I think based on 4 the Touhy, I'm not going to answer 5 that question. 6 BY MS. SWIFT: 7 Q. Your position today, 13 years 8 after this 2006 letter from the DEA to 9 Walgreens, your position today after you've 10 been hired by the plaintiffs' lawyers and 11 paid to offer opinions in this case is that 12 these pages of your report, these three pages 13 listing these requirements, are all obligated 14 by law; is that right, sir? 15 A. I think I've always believed 16 they were obligated by the law. I would 17 probably say in 2006, the environment in 18 regards to the opioid crisis and diversion, 19 probably the environments changed. 20 So I'm not sure that all of 21 these would have been something that I would 22 have used or been aware of at that time. 23 I think this is fluid and it's 24 changed over a period of years, but 25 generally, the answer to your question...</p>	<p style="text-align: right;">Page 458</p> <p>1 A. Well, I don't think they divert 2 drugs, but I -- 3 Q. That's not -- I'm sorry. If 4 that's what you heard me say, let me ask it 5 again. 6 A. Okay. 7 Q. That's not what I said. 8 As changes in how prescription 9 drugs are abused -- strike the question. 10 Trends in prescription drug 11 abuse have changed over time, fair? 12 A. That's correct. 13 Q. As those trends in prescription 14 drug abuse change, does the DEA change how it 15 addresses diversion of prescription drugs? 16 A. I think that's a logical 17 conclusion. One example would be the 18 Internet pharmacy epidemic that was started 19 in 1999, so I think there was a period of 20 time where there was a focus, and then 21 passing of the Ryan Haight law and 22 enforcement actions, that diversion -- 23 although, I'm not going to say today there's 24 not an illegal Internet pharmacy somewhere in 25 America. Obviously, the diversion shifted to</p>
<p style="text-align: right;">Page 457</p> <p>1 Q. It's your testimony that the 2 guidance the DEA has provided on suspicious 3 order monitoring has changed over time? 4 A. I don't know if it's guidance. 5 I think the environment of how diversion has 6 occurred has changed over time. So I think 7 my experiences and my opinions on what would 8 be required has changed over time because 9 it's a fluid situation, not static. 10 Q. You said the environment of how 11 diversion has occurred has changed over time. 12 By that do you mean, at least in part, that 13 the drugs that are typically diverted, those 14 have changed over time? 15 A. Many things have changed over 16 time. One is the type of drugs. Different 17 drugs have become a focus over different 18 periods of time. How they're diverted, 19 methods of how they're diverted. All of the 20 things have changed, and I'm sure in the 21 future will continue to change. 22 Q. As those changes in 23 prescription drug abuse occur over time, does 24 the DEA change how it addresses diversion of 25 those drugs?</p>	<p style="text-align: right;">Page 459</p> <p>1 a different kind of methodology, method or 2 type of drug, so yes. 3 Q. In fact, there are lots of 4 Internet pharmacies that are still operating 5 illegally in this country today, correct, 6 sir? 7 MR. FULLER: Object to form. 8 BY MS. SWIFT: 9 Q. If you know? 10 A. I don't know. 11 Q. In your report you don't 12 mention any guidance you provided to 13 Walgreens as a diversion investigator about 14 the right way to perform due diligence, 15 correct, sir? 16 A. My report doesn't say that, no, 17 ma'am. 18 Q. Your report does not mention 19 any guidance you provided to Walgreens about 20 how long to retain due diligence records, 21 correct, sir? 22 A. I think my report speaks to 23 that, but I don't think it speaks to it 24 specifically in the Walgreens section. 25 Q. The Walgreens section of your</p>

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1 report doesn't say anything about how long
2 Walgreens was supposed to retain due
3 diligence records, correct?
4 A. That's correct. I think that's
5 what I said in my answer.
6 Q. You're not going to come to
7 trial and say you provided Walgreens guidance
8 on how to perform due diligence for
9 potentially suspicious orders, correct, sir?
10 MR. FULLER: Object to form,
11 vague.
12 A. I'm not going to come to trial
13 and maybe say that specifically, but I'm sure
14 that I'm going to come to trial and say that
15 the DEA, through guidance, training,
16 distributor briefings, all registrants have
17 had ample opportunity to have -- come to that
18 same information.
19 But specifically that I would
20 have told Walgreens that, I'm not going to
21 say that at trial because that did not occur.
22 MS. SWIFT: I think we lost the
23 realtime feed, Mike.
24 THE VIDEOGRAPHER: Go off the
25 record, 9:00 a.m.

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1 (Recess taken, 9:00 a.m. to
2 9:03 a.m.)
3 THE VIDEOGRAPHER: Back on
4 record at 9:03 a.m.
5 BY MS. SWIFT:
6 Q. Sir, I believe the end of your
7 last question was that you are not planning
8 to come to trial and say that you ever told
9 Walgreens when you were a diversion
10 investigator monitoring the Perrysburg, Ohio
11 Walgreens facility, you're not going to come
12 and say that you ever told anybody at
13 Walgreens to keep their due diligence records
14 forever, correct?
15 A. I think my answer was a little
16 longer than that. I talked about what
17 Walgreens would have known independent, but I
18 believe I concluded that by saying I never --
19 I would never testify that I told them that
20 because it did not occur.
21 Q. Do you anticipate coming to
22 trial and talking about what Walgreens knew?
23 A. I think I would come to trial
24 and talk about what every registrant -- I
25 believe every registrant would know based on

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1 my experience and knowledge and training on
2 what was provided to them.
3 Q. And is that based on your
4 personal knowledge of nonpublic information
5 from your time at the DEA?
6 A. No, I don't think so. I think
7 there's public knowledge about the things I'm
8 speaking about today.
9 Q. But you're not going to come
10 and talk about what registrants knew based on
11 your personal knowledge from any nonpublic
12 investigations; is that fair?
13 A. If that's still restricted by
14 the Touhy authorization, then that would be a
15 correct statement, yes, ma'am.
16 Q. If it happens that the Touhy
17 authorization goes out the window, will you
18 agree to come back and answer more questions
19 so that we can get your testimony on these
20 points that you're not providing for us
21 today?
22 MR. FULLER: Object to form.
23 It will be up to the Special Master.
24 A. I was going to say, I don't
25 think that's up to my decision, but if it

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1 would be required of me, I would certainly do
2 that.
3 BY MS. SWIFT:
4 Q. All right. Let's go back to
5 the 2006 DEA letter to Walgreens that I
6 marked as Exhibit 19.
7 Do you have that in front of
8 you?
9 A. I do.
10 Q. The DEA's 2006 letter to
11 Walgreens says Walgreens was using a system
12 for suspicious order monitoring based on a
13 customer grouping formula, correct, sir?
14 A. Yes, ma'am.
15 Q. That's what you called it in
16 your report, right?
17 A. Well, this isn't my report. I
18 didn't author this, but that's what it says
19 in here.
20 Q. And when I said "your report,"
21 I meant in your actual expert report --
22 A. Oh, okay, you were talking
23 about this document. I'm sorry.
24 Q. The customer grouping formula
25 that is referenced in Exhibit 19, the 2006

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1 letter to Walgreens, you say at page 125 of
2 your report that Walgreens used that system
3 of reporting suspicious order monitoring --
4 strike the whole question.
5 Turn to page 125, please. You
6 see where it says Customer Grouping Formula
7 at the top of the page?
8 A. Yes, ma'am, I do.
9 Q. That's referring to the formula
10 that Walgreens was using to report suspicious
11 orders to the DEA and it's described in the
12 2006 DEA letter, correct?
13 A. I would agree, but I would say
14 that that's what they told me they were
15 doing.
16 Q. Understood.
17 A. Okay.
18 Q. That's what you were talking
19 about in your report when you said customer
20 grouping formula, you were talking about this
21 letter?
22 A. Yeah, but I just understood the
23 question to be that I knew that they were
24 actually doing this.
25 Q. Okay. Fine.

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1 A. That's just what they reported
2 to me that what they were doing.
3 Q. I'm just trying to tie what you
4 said in your report to this 2006 letter. Is
5 this -- this is the letter you were using to
6 write this section of your report on the
7 customer grouping formula, correct?
8 A. Yes. Yes, ma'am.
9 Q. Okay. You said in your report
10 that Walgreens used this customer grouping
11 formula to report suspicious orders until
12 around 2007, correct?
13 A. Yes.
14 Q. Walgreens then changed its
15 system for reporting suspicious orders after
16 receiving this 2006 letter from the DEA?
17 A. Yes, ma'am.
18 Q. In around 2007, you said in
19 your report: Walgreens modified its
20 reporting of suspicious orders to the DEA to
21 use a version of the formula described in
22 Appendix E(3) to the Chemical Handler's
23 Manual.
24 Correct?
25 A. That's what my report says,

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1 yes, ma'am.
2 Q. Walgreens used the E(3) formula
3 to report potentially suspicious orders from
4 2007 to 2012, correct?
5 A. Yes, that's what my report
6 says, yes, ma'am.
7 Q. Are you aware that those
8 reports are sometimes referred to as
9 excessive purchase records or ingredient
10 limit reports? There's different names that
11 are used?
12 A. There are different names, and
13 I'm aware of that.
14 Q. You would agree that the
15 formula in Appendix E(3) that Walgreens used
16 to report suspicious orders from 2007 to 2012
17 is not the same as the customer grouping
18 formula Walgreens was using in 2006?
19 A. I would agree, and also I would
20 like to comment on that, that it probably
21 actually was less effective than more
22 effective.
23 Q. I understand you have lots of
24 comments you'd like to give, and that's fine.
25 A. Okay.

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1 Q. My question is simply: Do you
2 agree with me that the formula in
3 Appendix E(3) that Walgreens used to report
4 suspicious orders from 2007 to 2012 is not
5 the same as the customer grouping formula
6 Walgreens was using in 2006?
7 A. Well, this statement just goes
8 to say that they used the same multiplier, so
9 the three multiplier is the same as the E(3)
10 as it is in the area referenced in the prior
11 time period.
12 Q. The two formulas are not the
13 same, correct, sir?
14 A. The formulas are not, but the
15 multiplier is.
16 Q. Okay. That's all I'm trying to
17 get an understanding from you is whether the
18 customer grouping formula that Walgreens was
19 using when it received the 2006 letter from
20 the DEA is the same or different from the
21 formula it changed to use afterwards?
22 A. There's no customer grouping in
23 the subsequent years --
24 Q. Thank you.
25 A. -- starting in 2007.

<p style="text-align: right;">Page 468</p> <p>1 Q. You didn't do -- well, strike 2 that. 3 You don't say in your report 4 that you or anyone else at the DEA ever told 5 Walgreens not to use the formula found in 6 Appendix E(3) of the Chemical Handler's 7 Manual, correct, sir? 8 A. Appendix E(3) was never 9 discussed in my presence with Walgreens. 10 Q. The DEA's 2006 letter to 11 Walgreens doesn't say not to use the E(3) 12 formula, correct? 13 A. I still stand by my previous 14 statement. The E(3) appendix was never 15 discussed by me or anyone in my presence the 16 whole time I was at Walgreens. 17 Q. And it's not mentioned in this 18 letter either? 19 A. It is not mentioned in that 20 letter. 21 Q. All right. I'd like you to 22 turn to page 40 of your report, please. Is 23 that 40? 24 A. I'm sorry. 25 Q. I believe you testified</p>	<p style="text-align: right;">Page 470</p> <p>1 statement. 2 BY MS. SWIFT: 3 Q. You testified yesterday that 4 you endorsed Flagging Method A, which you can 5 see at the top of page 41 of your report. 6 Because it -- is that correct? 7 A. I think that's an accurate 8 statement. It was -- I endorsed it because 9 it was utilized by the Masters 10 Pharmaceutical. 11 Q. Is that the only reason you 12 endorsed Flagging Method A? 13 A. No, that wouldn't be the only 14 reason, no, ma'am. 15 Q. Did any of the plaintiffs' 16 lawyers instruct or suggest to you that you 17 use Flagging Method A? 18 A. No. 19 Q. What other reasons did you 20 endorse Flagging Method A? 21 A. One, it was part of one of the 22 investigations I conducted, so I was familiar 23 with it. I believe it was discussed at an 24 administrative hearing with the DEA, 25 subsequently reviewed by the D.C. Court, and</p>
<p style="text-align: right;">Page 469</p> <p>1 yesterday that you did not review any of the 2 flagged orders from Dr. McCann's analysis; is 3 that correct? 4 A. I think my testimony in that 5 area was any specific orders. That would be 6 correct of what my testimony was, yes. 7 Q. You did not do any analysis to 8 see whether any specific suspicious order 9 caused the diversion of any specific pills 10 for nonmedical use, correct? 11 A. In regards to Dr. McCann's -- 12 Q. Correct. 13 A. That would be a correct 14 statement. I didn't do a specific order of a 15 specific drug, if I understand your question 16 properly. 17 Q. Well, you asked for a 18 clarification of whether I was speaking about 19 Dr. McCann's analysis. 20 You didn't do any analysis to 21 see whether any specific suspicious order 22 caused the diversion of any specific pills, 23 correct? 24 MR. FULLER: Object to form. 25 A. I think that's an accurate</p>	<p style="text-align: right;">Page 471</p> <p>1 there was a ruling on it from the D.C. Court 2 and also the one ruling that it was part of 3 this litigation, I think... 4 Q. Discovery Ruling 12? 5 A. Yes, Discovery Ruling 12. So I 6 think it's had some scrutiny. I think it 7 would be the proper one. And that's... 8 Q. What analysis, if any, did you 9 undertake to test each of the five flagging 10 methodologies and their ability to identify 11 suspicious orders? 12 A. Could you say that one more 13 time, please? 14 Q. Sure. 15 What analysis, if any, did you 16 do to test the five flagging methodologies in 17 your report and their ability to identify 18 suspicious orders? 19 A. I didn't personally do any 20 tests. I'm aware that they could have been 21 done by Dr. McCann, but I didn't personally 22 do them. 23 Q. Do you know whether Dr. McCann 24 conducted any analysis at all to test the 25 five flagging methodologies and their ability</p>

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1 to identify suspicious orders?
2 MR. FULLER: Object to form.
3 A. He had an extensive report.
4 I'm not sure on that. I believe he did, but
5 I'm not sure.
6 BY MS. SWIFT:
7 Q. Why do you believe Dr. McCann
8 did any analysis at all to test the five
9 flagging methodologies and their ability to
10 identify suspicious orders?
11 MR. FULLER: Object to form.
12 A. Well, I think that's what this
13 does.
14 BY MS. SWIFT:
15 Q. You think that's what what
16 does?
17 A. I think the methodology of A
18 identifies suspicious orders based on that
19 methodology, and then it provides them in
20 dosage units. So I think ultimately, for
21 these dosage units to appear on this page,
22 there had to be flagged suspicious orders.
23 Q. You're pointing to a page of
24 your report, not Dr. McCann's report,
25 correct, sir?

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1 A. Right. But -- yes. But for me
2 to see this --
3 MR. FULLER: Form.
4 A. -- I would have to know that
5 this methodology had flagged suspicious
6 orders because that's the only way the dosage
7 units could appear on this chart.
8 BY MS. SWIFT:
9 Q. Did you read Dr. McCann's
10 report?
11 A. I did.
12 Q. When did you read Dr. McCann's
13 report?
14 A. Sometime after he had submitted
15 it and reviewed his charts resulting from his
16 analysis.
17 Q. Did you read Dr. McCann's
18 report before you put together this section
19 of your report that appears at page 41?
20 A. No.
21 Q. Flagging Methodology A -- I'm
22 still at page 41 of your report. I'm going
23 to focus on the rows of these tables that
24 we've got here that relate to my client,
25 which is Walgreens, okay?

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1 A. Sure. Yes, ma'am.
2 Q. Flagging Methodology A flagged
3 95% of all Walgreens orders by dosage unit of
4 oxycodone and hydrocodone, correct, sir?
5 A. Yes, ma'am.
6 Q. Is it your professional opinion
7 to a reasonable degree of certainty that 95%
8 of Walgreens orders should not have been
9 shipped?
10 A. Based on the conduct of
11 Walgreens and the failure to do due diligence
12 on suspicious orders, yes, ma'am.
13 Q. Is it your opinion to a
14 reasonable degree of certainty that only 5%
15 of orders from Walgreens stores should have
16 been shipped and available to fill
17 prescriptions for Walgreens patients?
18 A. Well, that would be the
19 converse of this statement, but based on
20 their conduct -- I'll go back again, based on
21 their conduct and their failure to do
22 diligence after identification of suspicious
23 orders, the only conclusion I can draw is
24 that subsequent to that act, all of the
25 controlled substances were diverted.

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1 Q. So that's a yes, your opinion
2 is that only 5% of orders from Walgreens
3 stores should have been shipped and available
4 to fill prescriptions for Walgreens patients?
5 MR. FULLER: Object to form.
6 A. I really don't know because
7 Walgreens didn't conduct the proper due
8 diligence. But based on the methodology and
9 how I applied it, that's the results of the
10 methodology.
11 BY MS. SWIFT:
12 Q. You don't know whether it's
13 true that only 5% of orders from Walgreens
14 stores should have been shipped and available
15 for prescriptions to be filled for Walgreens
16 patients?
17 A. I guess you would draw that
18 conclusion based on 95.3% based on the
19 conduct of Walgreens, yes, ma'am.
20 Q. You would draw the
21 conclusion --
22 A. I would draw the conclusion
23 based on --
24 Q. Let me ask the question so the
25 record is clear.

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1 You would draw the conclusion
2 that only 5% of Walgreens orders should have
3 been shipped so that prescriptions could be
4 filled for Walgreens patients?
5 MR. FULLER: Object to form,
6 asked and answered. You've asked it
7 twice now or three times, probably.
8 A. Same as my previous statement.
9 Based on Walgreens' conduct in regards to
10 applying this methodology, that would be a
11 correct statement, yes, ma'am.
12 BY MS. SWIFT:
13 Q. You didn't do any analysis of
14 how many people would not have gotten their
15 medication if 95% of Walgreens orders had not
16 shipped, correct, sir?
17 A. I did not.
18 Q. You didn't do any analysis of
19 how many legitimate prescriptions would have
20 gone unfilled if 95% of Walgreens orders had
21 not been shipped, correct, sir?
22 A. I did not do that analysis, no,
23 ma'am.
24 Q. In your report, you don't offer
25 an opinion on the legitimacy of any of the

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1 other flagging methods you talk about,
2 correct?
3 A. That's correct.
4 Q. You didn't offer any criticisms
5 of any of the five flagging methods in your
6 report, correct, sir?
7 A. Oh, I think I did.
8 Q. Where did you offer criticisms
9 of any of the five flagging methods in your
10 report?
11 A. You're saying the
12 methodology --
13 Q. Correct.
14 A. -- for example, the three
15 times?
16 Q. There are five methodologies --
17 MR. FULLER: Go ahead and
18 finish your answer, Raf.
19 MS. SWIFT: Yes, I was
20 answering his question. There was no
21 pending question.
22 A. Yes. Throughout my report, I
23 think there's reviews of these methodologies,
24 and I think I'm critical of each of the
25 methodologies, with the exception of

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1 methodology of two times. I don't recall --
2 or I'm pretty confident that the two times
3 wasn't used by any of the distributors
4 listed. I used the two times as just a
5 stepdown from the three times to provide that
6 for the -- for the Court.
7 BY MS. SWIFT:
8 Q. Let me see if I understand what
9 you're saying.
10 When you say throughout your
11 report you provided criticisms of each of the
12 five flagging methodologies, do you mean in
13 the separate sections about the defendants?
14 A. Yes, ma'am.
15 Q. And I take it you mean when you
16 offered criticisms about whatever system each
17 defendant was using, that's what you mean by
18 criticizing these five flagging methodologies
19 that are discussed at page 41 through 46?
20 A. Well, yes, but I'd like to
21 clarify "criticism." I think my opinion is
22 steady throughout my report that using a
23 three-time methodology or three-time
24 threshold as a trigger point for suspicious
25 order is ineffective as part of a suspicious

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1 order system.
2 Q. You never told anybody that
3 when you were working as a diversion
4 investigator at the DEA, correct, sir?
5 MR. FULLER: Object to form.
6 BY MS. SWIFT:
7 Q. You don't say you did in your
8 report.
9 MR. FULLER: You can answer
10 based on your report.
11 A. Can I check something, one
12 second?
13 BY MS. SWIFT:
14 Q. If you can do it quickly.
15 A. I'll do it as quick as I can.
16 (Document review.)
17 A. I'm concerned about the Touhy
18 authorization, so I think I could answer that
19 question, but I think it would be something
20 that wouldn't be readily available, so I'm
21 concerned about answering, so...
22 BY MS. SWIFT:
23 Q. So if I understand you, sir,
24 you are refusing to answer the question
25 whether you ever told anyone, any

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1 distributor, when you were working as a
2 diversion investigator -- strike the
3 question. Hold on a second.
4 A. Can I speak to my counsel about
5 the --
6 Q. No, that's okay. We can move
7 on.
8 A. -- Touhy authorization --
9 Q. We can move on.
10 A. -- that I have a question, with
11 him?
12 Q. I don't have a lot of time, so
13 I'll just withdraw the last partial question
14 that I was just trying to ask --
15 A. Okay.
16 Q. -- and we'll move on.
17 Yesterday I believe you
18 testified that none of the five flagging
19 methods identified in your report are
20 suitable for suspicious order monitoring
21 systems.
22 Do you remember using the word
23 "suitable"?
24 A. I do. And I thought about that
25 testimony after I left yesterday, and I'd

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1 like to maybe correct it or make a statement
2 in regards to it.
3 Q. Well, let me just ask you.
4 What did you mean when you said none of the
5 five flagging methods that you identify in
6 your report are suitable for suspicious order
7 monitoring systems?
8 A. Well, specifically how they
9 would identify a suspicious order, two times,
10 three times, the 8,000 and the pickers and
11 packers program or the -- I think I don't use
12 that particular name -- the one -- the one
13 that I think that statement would indicate
14 that I would say that the Masters was not
15 suitable, and I -- I would disagree.
16 If I made that statement and
17 said that one was, I'd like to correct that
18 and say that I -- this would be a suitable --
19 potentially suitable suspicious order
20 program.
21 Q. The Masters method that
22 identified 95% of Walgreens orders as
23 suspicious, that one is suitable? Is that
24 your testimony, sir? But none of the other
25 ones?

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1 A. Just the trigger of the
2 six-month threshold, maximum monthly, just
3 the trigger that would identify the
4 suspicious order, that was, I believe, the
5 question I answered. That methodology, not
6 the subsequent failure to do due diligence
7 and the identification of orders that
8 resulted from that.
9 Q. My question was whether it's
10 your testimony that the Masters method, the
11 one that identified 95% of Walgreens orders
12 as suspicious, is the only one of your five
13 flagging methods that you believe is suitable
14 for identifying suspicious orders, yes or no,
15 please?
16 MR. FULLER: Object to form,
17 vague.
18 A. As a trigger mechanism or
19 threshold to establish that, an order as
20 being potentially suspicious, I would answer
21 yes to that question.
22 BY MS. SWIFT:
23 Q. You've referred a couple of
24 times to this trigger mechanism, and I take
25 from your testimony that you're referring to

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1 the aspect of your methodology whereby after
2 the first order is flagged as suspicious, it
3 triggers every subsequent order to be flagged
4 as suspicious; is that correct, sir?
5 MR. FULLER: Form, misstates
6 his report.
7 A. No.
8 BY MS. SWIFT:
9 Q. What do you mean by a trigger
10 mechanism?
11 A. A threshold event. Every
12 suspicious order system has to identify an
13 order, so that would be -- and I'm sorry if
14 that terminology is unfamiliar to you. That
15 would be a trigger event or a threshold event
16 or something that stops the distribution of
17 an order and requires the registrant to take
18 some action; the unusual size, the unusual
19 frequency or deviating from a --
20 substantially from a pattern.
21 Q. Besides the five flagging
22 methods that you identify in your report,
23 there may be other methods of identifying
24 suspicious orders that registrants use in the
25 real world, correct, sir?

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1 A. Yes, there could be.
 2 Q. And those other methods that
 3 are not identified in your report might be
 4 perfectly sufficient for identifying
 5 suspicious orders, correct, sir?
 6 A. I hope for the sake of
 7 diversion they are perfect and they do exist,
 8 but yes, that's a possibility.
 9 Q. And, in fact, you testified
 10 yesterday, I believe, that it's up to the
 11 registrant to design a system that makes
 12 sense for that registrant's business,
 13 correct, sir?
 14 A. That's correct.
 15 Q. When you were at the DEA, you
 16 never advised a registrant to follow any of
 17 the five flagging methods that are addressed
 18 in your report, correct, sir?
 19 MR. FULLER: Same instruction
 20 on Touhy.
 21 MS. SWIFT: Are you going to
 22 follow your counsel's instruction not
 23 to answer that question, sir?
 24 THE WITNESS: I'd like to think
 25 about it first. Is that okay?

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1 MS. SWIFT: Depends on how long
 2 it takes.
 3 THE WITNESS: Yeah, I think
 4 I'll use the Touhy letter and not
 5 answer that question.
 6 BY MS. SWIFT:
 7 Q. Did you analyze any other
 8 flagging methods for identifying suspicious
 9 orders besides the five that are discussed in
 10 your report?
 11 A. No, ma'am, I didn't provide any
 12 other methodologies to Mr. McCann if that's
 13 the question.
 14 Q. Turning back to page 41 of your
 15 report, we've got these tables showing a
 16 number and a percentage of flagged orders of
 17 both oxycodone and hydrocodone by dosage
 18 unit, correct, sir?
 19 A. Yes, ma'am.
 20 Q. These tables are broken out by
 21 county, correct, sir?
 22 A. Yes, they are.
 23 Q. These tables are further broken
 24 out for five of the defendants in this case,
 25 right?

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1 A. Yes.
 2 Q. You show aggregated numbers for
 3 each defendant for oxycodone and hydrocodone,
 4 correct?
 5 A. Yes, I do.
 6 Q. All right. I'm going to focus
 7 on Walgreens. You provide one number for
 8 flagged orders of oxycodone into Cuyahoga
 9 County, right?
 10 MR. FULLER: Are you looking at
 11 the first methodology?
 12 MS. SWIFT: Yeah, the
 13 40 million and some odd.
 14 A. Yes, ma'am.
 15 BY MS. SWIFT:
 16 Q. Then you do the same thing for
 17 Summit County below, correct, sir?
 18 A. Yes, ma'am.
 19 Q. You provide one number for
 20 Walgreens shipments of oxycodone into Summit,
 21 right?
 22 A. Yes, ma'am.
 23 Q. You provide one number for
 24 Walgreens shipments of hydrocodone into
 25 Summit, correct?

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1 A. Yes, ma'am.
 2 Q. And then you do the same thing
 3 for all five of the flagging methods,
 4 correct?
 5 A. That's correct.
 6 Q. You don't break down the
 7 numbers by any individual pharmacy in your
 8 report, correct?
 9 A. I do not.
 10 Q. You did not perform any
 11 analysis to show how many orders were flagged
 12 at any individual Walgreens pharmacy,
 13 correct?
 14 A. I do not show that in my
 15 report, but I know that that has to exist
 16 because it's obviously part of the analysis
 17 done by Dr. McCann.
 18 Q. Have you seen it?
 19 A. I have not.
 20 Q. Do you know for a fact whether
 21 McCann did any flagging analysis on a
 22 pharmacy-by-pharmacy basis?
 23 A. So I'd like to answer that by
 24 saying -- when you say I know by a fact, I
 25 would know through the analysis of the ARCOS

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1 data that it would have to indicate specific
 2 orders which would identify those pharmacies.
 3 Now, whether he looked at them
 4 specifically to that pharmacy, but based on
 5 your question, just the analysis of the ARCOS
 6 data, that -- that actually would occur
 7 because each order would be specific to a
 8 pharmacy.
 9 He didn't -- if I understand
 10 your question, he didn't look at them in
 11 terms of each specific pharmacy, but the
 12 nature of the analysis, it is by the pharmacy
 13 by the orders.
 14 Q. You did not perform an analysis
 15 to see whether Walgreens performed diligence
 16 on any of the actual orders that flagged on
 17 any of your five methodologies in
 18 Mr. McCann's analysis, correct?
 19 A. Well, my investigation and
 20 opinion of Walgreens does state that in
 21 regards to the due diligence topic.
 22 Q. Listen to my question. That's
 23 not what I'm asking about.
 24 A. Okay.
 25 Q. We'll get to the stuff you say

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1 in your report about the due diligence that
 2 Walgreens did.
 3 You didn't perform an analysis
 4 to see whether Walgreens performed diligence
 5 on any of the specific orders that flagged on
 6 any of these five methodologies, correct,
 7 sir?
 8 A. I'm not aware of any due
 9 diligence for those orders, that's correct.
 10 Q. That's not what I asked.
 11 A. I didn't -- I didn't
 12 specifically go to McCann's report and look
 13 at each order of Dr. McCann's and try to find
 14 due diligence. I just looked at the scope of
 15 the due diligence by Walgreens.
 16 Q. You didn't go to Dr. McCann's
 17 report and look at any order of -- that
 18 flagged on any of the analyses.
 19 A. That's a correct statement.
 20 Q. For any of the five flagging
 21 methods that you talk about, did you consider
 22 the impact of stocking a new store's shelves?
 23 A. I did not take that specific
 24 incident into consideration, but in my review
 25 of due diligence records, I didn't find

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1 anything that would indicate that that had
 2 occurred.
 3 Q. Did you consider whether any of
 4 the five flagging methods that you talk about
 5 could flag an order for a store before the
 6 store even opened for business, just based on
 7 the stocking of the store's shelves? Do you
 8 know whether that happened?
 9 A. I'm not aware that that had
 10 happened.
 11 Q. Did you read Dr. McCann's
 12 testimony from this past Friday that using at
 13 least some of these five flagging methods, an
 14 order to stock a new store's shelves could be
 15 flagged?
 16 A. I don't recall reading that in
 17 his testimony, no, ma'am.
 18 Q. Did you read his testimony yet?
 19 I know it was just the other day.
 20 A. I've read so many. I don't
 21 believe so.
 22 Q. I will represent to you, and
 23 you can check the transcript, that Dr. McCann
 24 testified that for low-volume stores, the
 25 store might never have another order as big

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1 as the first order to stock the shelves
 2 again; but under all of the flagging methods,
 3 once the first order is flagged, every single
 4 order after that is also flagged, correct,
 5 sir?
 6 MR. FULLER: Form, compound.
 7 MS. SWIFT: Do you understand
 8 the question?
 9 THE WITNESS: Yeah, I
 10 understand the question.
 11 A. And I think that possible
 12 scenario exists, but the issue would be that
 13 if that was to occur and it would trigger a
 14 suspicious order, there would be a sufficient
 15 due diligence to dispel that suspicion. And
 16 if I didn't see that, it couldn't be taken
 17 into account by the methodology.
 18 BY MS. SWIFT:
 19 Q. If it your opinion that due
 20 diligence is required on orders that are
 21 needed to stock a new Walgreens store's
 22 shelves?
 23 A. Only if it triggers a
 24 suspicious order.
 25 Q. Now, this is going to

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1 admittedly be a hypothetical question, but
 2 I'd like you to assume with me -- we're going
 3 to talk about a new Walgreens store.
 4 Assume with me, please, sir,
 5 that Walgreens had made sure the new store
 6 was registered with the DEA and Walgreens
 7 understood the customer base of the new store
 8 because Walgreens' real estate department had
 9 picked the location, and Walgreens' inventory
 10 management system had figured out that the
 11 new store needed 8500 dosage units of oxy 30
 12 to stock its shelves, and that's how many
 13 dosage units the store ordered to stock its
 14 shelves.
 15 Are you with me?
 16 A. I'm following your scenario so
 17 far.
 18 Q. In that case, would it be
 19 appropriate to flag that first order under
 20 any of the five flagging methods that you
 21 have discussed in your report?
 22 A. If the order would have
 23 triggered the methodology, then it would be
 24 appropriate to be flagged.
 25 Q. And in that case, if that first

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1 order was flagged when the store was stocking
 2 its shelves, is it your opinion that all of
 3 the store's later orders should also be
 4 flagged after the first order, even if they
 5 never exceeded 8,000 units again or any --
 6 they never flagged on any methodology ever
 7 again?
 8 A. Well, the hypothetical that you
 9 provided to me would be one instance, and the
 10 methodology and the resulting all orders for
 11 lack of due diligence, that's based on the
 12 systematic failure by the registrants. So
 13 just one incident, I don't believe would
 14 change the numbers or the methodology.
 15 For example, as I discussed
 16 yesterday, there's a possibility, I guess,
 17 that there was one due diligence
 18 investigation that might be suitable, but if
 19 it was a systematic failure to do due
 20 diligence, then, no, it would not change
 21 these numbers.
 22 Q. You did not do any analysis of
 23 Dr. McCann's charts to see how often a
 24 store's first order to stock its shelves
 25 flagged under one of the flagging methods,

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1 correct, sir?
 2 A. I did not, but I also don't
 3 recall in looking -- finding any due
 4 diligence that would indicate that that
 5 occurred.
 6 Is that a hypothetical question
 7 or --
 8 Q. No. Maybe you didn't
 9 understand my question.
 10 I just want to know whether you
 11 did any analysis of Dr. McCann's results to
 12 see how often a store's very first order to
 13 stock its shelves flagged on one of the five
 14 flagging methods?
 15 A. It would be impossible to know
 16 that by just looking at the ARCOS data.
 17 Q. It's your testimony that it
 18 would be impossible to figure out how often a
 19 store's first order to stock its shelves
 20 flagged on one of the five flagging methods?
 21 A. I believe your question was a
 22 new store.
 23 Q. Fair. Let me reask it.
 24 You didn't do any analysis of
 25 Dr. McCann's results to see how often the

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1 first order placed by a store that appears in
 2 the ARCOS data flagged under one of the five
 3 methodologies, correct?
 4 A. You have to ask that one more
 5 time.
 6 Q. You didn't do any analysis of
 7 Dr. McCann's results to see how often a
 8 store's first order that appears in the ARCOS
 9 database flagged on one of the five flagging
 10 methods?
 11 A. Well, I'm aware under the
 12 flagging mechanisms, a first order wouldn't
 13 trigger Methodology A, Methodology B,
 14 Methodology C. If it was over 8,000, it
 15 would trigger Methodology D. And I'd have to
 16 go back to the maximum daily dosage units,
 17 but I don't think it would trigger an order
 18 there. Because a first order hasn't
 19 established the 6- or 12-month average.
 20 So I believe under those
 21 methodologies, it would not trigger under
 22 Dr. McCann's analysis.
 23 Q. You did not do any analysis of
 24 Dr. McCann's results to see how often a
 25 store's first order that appears in the ARCOS

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1 database flagged under one of the flagging
2 methods, correct? Not whether it's possible,
3 just how often that happened?
4 A. No, I did not.
5 Q. Okay.
6 A. Because as my previous answer,
7 under those methodologies, it wouldn't
8 matter.
9 Q. Let's go to page 46 of your
10 report, please, sir. You say on page 46 that
11 you only presented data to an economist for
12 Flagging Method A, the Masters method,
13 correct?
14 MR. FULLER: Where are you
15 reading from, Counsel?
16 A. I don't think I said that. I
17 think this statement is in relation to the
18 correction of my testimony that this is the
19 one system that I provide an opinion on that
20 has a reasonable degree of certainty that...
21 BY MS. SWIFT:
22 Q. Did you provide any of the data
23 that appears in your report to an economist?
24 MR. FULLER: Object to form.
25 A. I don't recall doing that. I

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1 do not believe so, no.
2 BY MS. SWIFT:
3 Q. Do you have any understanding
4 about whether any of the data that appears in
5 your report was going to be passed on by the
6 plaintiffs' lawyers to some economist to make
7 use of that data?
8 A. I believe there's a statement
9 of that in my report somewhere, that it could
10 be used.
11 Q. Do you know whether that ever
12 happened?
13 A. I don't believe it's happened.
14 If it has happened, no one's advised me.
15 Q. Have you ever had a
16 conversation with any economist working for
17 the plaintiffs' lawyers about the data that
18 appears in your report?
19 A. No, ma'am.
20 Q. You testified --
21 A. Can I just correct that a
22 little bit?
23 So in the course of meetings,
24 I've talked to a lot of people. No one ever
25 I've talked to has identified themselves as

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1 an economist or I've never talked to anyone
2 with the purpose of giving these things to an
3 economist. So I don't want to imply my
4 testimony is I've never talked to an
5 economist. I'm not aware of it, but I'm just
6 kind of protecting the fact that if I did, I
7 wasn't even aware of it.
8 Q. You never explained the data in
9 your report to anyone for the purpose of them
10 taking that data and using it to calculate
11 damages in this litigation?
12 A. I have never done that.
13 Q. You testified yesterday that
14 you provided the five flagging methods
15 discussed in your report -- you provided
16 those to plaintiffs' counsel by phone I
17 believe, you said to -- provided them to
18 Mr. Farrell.
19 Do you remember that testimony?
20 A. I think that question was the
21 first time that I talked to somebody about
22 it. So --
23 Q. I'm trying to get at how the --
24 MR. FULLER: Object to the form
25 of the last question. I'm sorry.

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1 BY MS. SWIFT:
2 Q. I'm trying to get at how the
3 five flagging methods made their way from you
4 to Dr. McCann.
5 Do you have any idea how that
6 happened?
7 A. There was a couple of different
8 discussions with the plaintiff attorneys.
9 I'm not sure who relayed it to Dr. McCann. I
10 discussed it with Paul Farrell, Mr. Farrell a
11 couple of times; also with Mr. Fuller. I'm
12 not sure who relayed it to him, but I
13 discussed the methodologies and how I wanted
14 them applied.
15 Q. All of those conversations were
16 verbal, is that correct, not in writing?
17 A. There was nothing in writing,
18 and they were verbal, either in person or on
19 a telephone.
20 Q. I'm going to hand you what I'll
21 mark as Exhibit 20.
22 MS. SWIFT: And, Counsel, I
23 apologize, I only have one extra copy.
24 Blame the hotel. I'm not even going
25 to have a copy for myself.

<p style="text-align: right;">Page 500</p> <p>1 (Whereupon, Deposition Exhibit 2 Rafalski-20, Plaintiffs' Responses to 3 the Amended and Clarified Discovery 4 Ruling 12 Supplemental Interrogatory 5 Issued to Plaintiffs, was marked for 6 identification.) 7 BY MS. SWIFT: 8 Q. Do you have that in front of 9 you, sir? 10 A. I do. 11 THE WITNESS: Trade you. 12 Sorry. 13 BY MS. SWIFT: 14 Q. Well, first of all, have you 15 ever seen the document that I've marked as 16 Exhibit 20? 17 A. I have, yes, ma'am. 18 Q. The document I marked as 19 Exhibit 20 is a set of interrogatory 20 responses served by the plaintiffs on 21 January 25th, 2019, and if you go to -- I 22 believe it's the sixth page -- there's a list 23 of flagging methodologies prepared at the 24 very end of the written interrogatory 25 response. Keep going.</p>	<p style="text-align: right;">Page 502</p> <p>1 Q. Okay. All right. Turning back 2 to your report -- you can set that aside, 3 we're done with it -- page 42, I'd like to 4 take a look at, please. 5 MR. FULLER: I'm sorry, 6 Counsel, what page? 7 MS. SWIFT: 42. 8 BY MS. SWIFT: 9 Q. If you had picked Flagging 10 Method B that's identified at the top of 11 page 42, instead of Method A, the Masters 12 method, what data would you have presented 13 for Walgreens? 14 MR. FULLER: Object to form. 15 A. I don't understand that 16 question. 17 BY MS. SWIFT: 18 Q. Fair enough. 19 A. I think I did pick 20 Methodology B, but so I don't understand. 21 Q. Well, you said you endorsed 22 Method A and that's the only method you 23 endorsed, correct, because of the Masters 24 case and some other reasons? 25 A. Well, I think I make that</p>
<p style="text-align: right;">Page 501</p> <p>1 MR. FULLER: It's not page 2 numbered. 3 MS. SWIFT: I noticed that, 4 Mike. 5 MR. FULLER: We'll blame 6 Mr. Moody or Mr. Farrell. 7 BY MS. SWIFT: 8 Q. Do you have a list in front of 9 you, Mr. Rafalski, that lists five flagging 10 methodologies in the plaintiffs' 11 interrogatory response from January 25th? 12 A. I do. 13 Q. Are these your five flagging 14 methodologies? 15 A. Yes, ma'am. 16 Q. Which one is based on the 17 Masters case? 18 A. 4. 19 Q. Am I correct based on your 20 testimony today and yesterday that you're not 21 planning to come to trial and offer testimony 22 about any of the flagging methods except the 23 Masters method? 24 A. No, I don't think that's my 25 testimony.</p>	<p style="text-align: right;">Page 503</p> <p>1 statement at the conclusion that we had 2 discussed -- 3 Q. Right. 4 A. -- in regards to the Masters. 5 Q. Right. On page 46 you endorse 6 the Masters method, Method A, correct, sir? 7 A. Well, I don't know that I 8 endorse the system. I say that applying the 9 tests set forth in the Masters provides a 10 reasonable estimate and initial trigger. I 11 say there's a reasonable. I don't know that 12 I would say that it's an endorsement. I say 13 that because in my -- extensively in my 14 training and in publications, DEA doesn't 15 endorse suspicious order systems. 16 Q. You say in your report that you 17 are selecting Methodology A because of your 18 understanding that this litigation will be 19 advanced by selecting a methodology 20 quantifying a volume of pills that entered 21 CT1 jurisdictions, that's Summit and Cuyahoga 22 County, unlawfully and providing this data to 23 an economist to measure the harm caused by 24 this volume. 25 Correct, sir?</p>

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1 A. Yes.

2 Q. If you had picked Method B

3 instead of Method A, the data you would have

4 presented would have been very different,

5 correct, sir?

6 A. I wouldn't have picked that

7 method because it wouldn't be a reasonable

8 degree -- or it wouldn't have been a

9 suspicious order system that I would have

10 ever approved or not made comment on.

11 My opinion is that a fixed two

12 times a 12-month average would not be a

13 methodology that I would ever say to move

14 forward to be considered by the Court.

15 Q. I'm going to ask you with

16 respect, sir, to please listen to my

17 questions.

18 A. Okay.

19 Q. You picked --

20 A. Can I just --

21 Q. Go ahead.

22 A. It would be different results.

23 I would -- if that's the answer you want,

24 then the methodology of the A -- obviously,

25 it would be different results.

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1 Q. Method A, the Masters method,

2 identified 95% of Walgreens orders for

3 oxycodone and hydrocodone as suspicious,

4 correct, sir?

5 A. Yes, that's what the chart

6 says.

7 Q. If you had picked Method B,

8 that method identified just 49% of Walgreens

9 orders for oxycodone into Cuyahoga County as

10 suspicious, correct, sir?

11 A. That's what the information

12 says in the analysis.

13 Q. The number is different for

14 hydrocodone. If you had picked Method B,

15 that method identified 23% -- 23.7% of

16 Walgreens hydrocodone orders as suspicious,

17 correct, sir?

18 A. Yes. But again, I'm going

19 to restate. I would not have picked -- I

20 mean, I'm not going to disagree that the

21 figures are different, but I would not have

22 picked that.

23 Q. I get it.

24 A. But if I would have picked it,

25 they would be different.

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1 Q. Understood.

2 A. Okay. All right.

3 Q. You didn't pick Method B. You

4 picked Method A, that it flagged 95% of

5 Walgreens orders.

6 A. I didn't pick it because of the

7 percentage --

8 Q. Okay.

9 A. -- the percentage of how many

10 they flagged was not the factor that I used

11 to pick that. It was because of the review

12 by the D.C. Court and my familiarity with the

13 case, and the fact that I would see that that

14 could be a viable suspicious order trigger.

15 Q. If you had picked Method C,

16 which you can see on page 43 of your report,

17 you would have identified just 1.5% of

18 Walgreens orders for oxycodone in Cuyahoga

19 County as suspicious, correct, sir?

20 A. I do agree that that's the

21 number that it would have identified, but I

22 also would like to state it would be expected

23 that it would decrease because that's -- as

24 my opinion states, is ineffective three

25 times --

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1 Q. You didn't --

2 A. -- trigger.

3 Q. You can't vouch for the

4 accuracy of any of the numbers that appear in

5 these tables at pages 41 to 45 of your

6 report, correct, sir?

7 A. Mr. McCann would have to

8 testify to the accuracy. He did the

9 analysis.

10 Q. You just relied on what

11 Mr. McCann provided, correct, sir?

12 A. Yes, I did.

13 Q. You were -- strike that.

14 You don't have an opinion about

15 whether any particular order that you

16 identified or that Dr. McCann identified as

17 suspicious was diverted to an illicit

18 channel, correct, sir?

19 A. Well, I think based on the

20 methodologies and the lack of due diligence,

21 I think my -- these say that those were

22 diverted.

23 Q. My question was a little bit

24 different.

25 A. Okay.

<p style="text-align: right;">Page 508</p> <p>1 Q. You don't have an opinion about 2 whether any particular order -- you didn't 3 look at any particular order to see whether 4 it was diverted to an illicit channel? 5 A. I did not -- 6 Q. Okay. 7 A. -- analyze all the orders and 8 try to find one or locate one that was 9 diverted. 10 Q. You didn't analyze any of the 11 orders, correct, sir? 12 A. That's correct. 13 Q. You have no opinion about 14 whether any particular order that was flagged 15 as suspicious led to someone's addiction, 16 overdose or death, correct, sir? 17 A. As of today, I have no opinion 18 on that matter. 19 Q. Do you plan on coming up with 20 that opinion at some point after today? 21 A. I can't rule that out if I'm 22 asked to look at that or I'm provided some 23 information I could review that would -- that 24 would indicate that. So I can't rule out 25 that that would occur.</p>	<p style="text-align: right;">Page 510</p> <p>1 A. Based on my experience in 2 having discussions with pharmacists, I 3 believe its possible for a pharmacist to 4 refuse to fill a prescription. 5 Q. You don't offer any opinions in 6 your report about a pharmacist's professional 7 obligations, correct, sir? 8 A. That's correct. 9 Q. You are not a pharmacist? 10 A. I'm not a pharmacist. 11 Q. Have you ever worked at a 12 pharmacy? 13 A. I have not. 14 Q. Turn to page 114, please. This 15 is the start of the section of your report on 16 Walgreens, correct? 17 A. Okay. Yes. 18 Q. Do you see that table about 19 halfway down the page? 20 A. Yes. 21 Q. That table shows your 22 understanding of the overall volume of 23 shipments of oxycodone and hydrocodone from 24 Walgreens distribution centers to Walgreens 25 pharmacies, correct?</p>
<p style="text-align: right;">Page 509</p> <p>1 Q. If a prescription was 2 legitimate, the pharmacist was obligated to 3 fill it, correct, sir? 4 MR. FULLER: Form. 5 A. I don't think the DEA speaks to 6 that, whether they're obligated to fill a 7 prescription. 8 BY MS. SWIFT: 9 Q. Do you know one way or the 10 other whether -- 11 A. If the DEA speaks to that 12 topic? 13 Q. No, sorry. 14 Do you know whether pharmacists 15 are obligated by their professional 16 responsibilities to fill prescriptions that 17 they have determined are legitimate? Maybe 18 you don't know one way or the other. 19 A. Let me think. I don't know 20 that, the answer to that question. 21 Q. All right. Turn, if you would, 22 please, to page 114 of your report. 23 A. Can I qualify my last answer, 24 quickly? 25 Q. Sure.</p>	<p style="text-align: right;">Page 511</p> <p>1 A. Yes, it does. 2 Q. Do you see footnotes 489 and 3 490? 4 A. Yes, I do. 5 Q. You cite in those footnotes to 6 Dr. McCann's Appendix 10 for Walgreens' 7 volume numbers, correct? 8 A. Yes. 9 Q. I'm going to hand you what I'll 10 mark as Exhibit 21. 11 (Whereupon, Deposition Exhibit 12 Rafalski-21, Excerpt from McCann 13 Appendix 10, was marked for 14 identification.) 15 BY MS. SWIFT: 16 Q. And I've put a Post-it on the 17 front of the exhibit version of this that 18 says what it is. It's an excerpt of McCann's 19 Appendix 10, because his appendices are 20 giant. 21 A. They are. 22 Q. What we did was we pulled out 23 the pages that relate to Walgreens. Okay. 24 You cite in your report to 25 pages 226 of Appendix 10 and page 856 of</p>

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1 Appendix 10, correct?
2 A. Yes, I do.
3 Q. And you can see the first page
4 of what I just handed you is page 226 of
5 1260. Is that the page that you were citing
6 in footnote 489?
7 A. Yes.
8 Q. And then if you'll turn to
9 page 46 of what I just handed you, can you
10 confirm for me that that is page 856 that you
11 cited in your report?
12 A. Page 46. You mean page -- I'm
13 sorry, page 856?
14 Q. I'm sorry. To make this
15 easier -- this was the theory, anyway -- we
16 added page numbers at the bottom right.
17 A. Okay.
18 Q. So turn to page 46, and it's
19 double sided.
20 A. Oh, all right. I was confused
21 when you said -- I was looking for the...
22 okay.
23 Q. Is page 46 also page 856 of
24 1260?
25 A. Yes, ma'am.

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1 Q. Is that the page 856 that you
2 cite in your report at page 114?
3 A. Yes, ma'am.
4 Q. Okay. This Appendix 10 from
5 McCann's report is what you relied on to
6 determine total volume of oxycodone and
7 hydrocodone that Walgreens shipped into
8 Cuyahoga and Summit Counties; is that right?
9 A. Yes, ma'am.
10 Q. You only talk about oxycodone
11 and hydrocodone in your report, correct?
12 A. Yes, ma'am.
13 Q. Am I right that you don't have
14 any opinions about any other opioid pain
15 medications besides oxy and hydro?
16 A. As of today I do not because I
17 was not requested to do any analysis on those
18 other drugs.
19 Q. After -- turn back to page 1 of
20 Exhibit 21. The page 1 of Exhibit 21 is a
21 table that shows overall numbers, Total
22 Shipments to Cuyahoga identified by
23 Methodology, Common Sense Method, Maximum
24 Monthly Trailing Six-Month Pharmacy Specific
25 Threshold, Walgreens to All Buyers, 1996 to

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1 2018, correct?
2 A. Yes.
3 Q. And it's a table that shows
4 numbers broken out by drug and by
5 transaction, dosage units, MME, and base
6 weight, correct?
7 A. Yes.
8 Q. After the table on page 1 of
9 Appendix 10, there's a series of bar graphs
10 showing, in the aggregate, Walgreens
11 shipments of oxy and hydro to its pharmacies
12 in the aggregate, correct?
13 A. Yes, ma'am.
14 Q. None of these charts shows any
15 data for any individual Walgreens pharmacy,
16 correct?
17 MR. FULLER: Object to form.
18 A. That's an accurate statement,
19 but they're all built upon individual orders.
20 BY MS. SWIFT:
21 Q. I understand.
22 A. Okay.
23 Q. I'm just saying, when you're
24 flipping through Dr. McCann's charts that
25 display the results of his flagging

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1 methodologies, you can't tell anything about
2 any individual pharmacy, correct?
3 A. I cannot by looking at these
4 charts.
5 Q. Do you know how many Walgreens
6 stores there are in Cuyahoga County?
7 A. I do not.
8 Q. How about Summit County?
9 A. I do not.
10 Q. Do you know anything about the
11 geographic locations of any of Walgreens'
12 pharmacies in Summit or Cuyahoga County,
13 other than the fact that they're in those
14 counties?
15 A. It doesn't appear in my
16 opinion, but during my review of data, I did
17 at one point take a look by just using the
18 Internet, Googling and looking at some of the
19 locations, but I didn't formulate a report on
20 that.
21 So I won't say that I never did
22 that, but I don't have any records or
23 documents that would record exactly the
24 distances and the locations.
25 Q. You also didn't include in your

<p style="text-align: right;">Page 516</p> <p>1 report anything about the specific customer 2 base for any individual Walgreens pharmacy, 3 correct, sir? 4 A. I did not. 5 Q. Do you know how many of the 6 Walgreens pharmacies in Cuyahoga and Summit 7 County are on corner lots? 8 A. I do not. 9 Q. Do you know how many of the 10 Walgreens pharmacy in Summit and Cuyahoga 11 Counties are freestanding locations with 12 their own dedicated parking and a 13 drive-through window? 14 A. I do not. 15 Q. Do you know how much oxycodone 16 or hydrocodone Walgreens distribution centers 17 shipped to any one of those Walgreens 18 pharmacies? 19 A. I do not. I had not done that 20 analysis up to today. 21 Q. You can't tell any of that from 22 the charts that are in Appendix 10, correct, 23 sir? 24 A. That's correct. 25 Q. All right. You can set that</p>	<p style="text-align: right;">Page 518</p> <p>1 Walgreens depositions where Walgreens 2 witnesses talked about the kind of due 3 diligence that had been done? 4 A. I read depositions or specific 5 parts of depositions relating to my report. 6 I -- you know, my training and experience has 7 said that if it's not written down, it 8 doesn't exist. It needs to be documented. 9 So how I would look at that 10 kind of due diligence, if it was not a 11 recorded due diligence and there wasn't a 12 historical record, and it's not available for 13 future review for other incidences, I 14 wouldn't consider -- I mean, I'm not going to 15 deny that it would have occurred or would not 16 have occurred, but it's really not due 17 diligence if it's not recorded in a due 18 diligence file. 19 Q. Well, there's a couple of 20 things going on in that answer. 21 A. Sure. 22 Q. I take from your testimony that 23 you are assuming, if Walgreens no longer 24 retains a document today, that that means 25 that document never existed, correct?</p>
<p style="text-align: right;">Page 517</p> <p>1 one aside. 2 Turn, if you would, please, 3 sir, to page 117 of your report. This is a 4 section within the Walgreens section about 5 the due diligence that you believe Walgreens 6 conducted, correct? 7 A. Yes, ma'am. 8 Q. Now, as I understand it, it's 9 your opinion that because you only saw a 10 limited number of e-mails about due diligence 11 that Walgreens performed 10, 12, 13 years 12 ago, that that means Walgreens performed no 13 other due diligence; is that correct? 14 A. Not that was brought to my 15 attention in trying to formulate my opinion. 16 Q. And in formulating your 17 opinion, you determined that Walgreens had 18 only conducted limited due diligence because 19 you only saw documentation of limited due 20 diligence, correct? 21 A. That's the only basis I could 22 use to form my opinion. 23 Q. You based your -- well, let me 24 ask you this. 25 Did you read any of the</p>	<p style="text-align: right;">Page 519</p> <p>1 A. In my experience as a diversion 2 investigator, in conducting an investigation 3 or forming an opinion, yes, it doesn't exist. 4 Q. Are you basing your opinion 5 that Walgreens did limited due diligence on 6 the documents cited in your report at 7 footnotes 499 and 500? 8 MR. FULLER: Object to form. 9 A. I believe I also cite 501, but 10 yes, ma'am. 11 BY MS. SWIFT: 12 Q. Is that it, though, in terms of 13 the support you have for your opinion that 14 Walgreens performed limited due diligence is 15 based on the documents cited in notes 499, 16 500 and 501? 17 A. Yeah, and the fact that they 18 didn't produce any prior to 2011, yes, ma'am. 19 Q. I'll hand you one of those 20 documents that we'll mark as Exhibit 22. 21 (Whereupon, Deposition Exhibit 22 Rafalski-22, E-mail(s), 23 WAGFLDEA00000459 - WAGFLDEA00000460, 24 was marked for identification.) 25 ///</p>

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1 BY MS. SWIFT:
2 Q. All right. I've handed you a
3 July 8th, 2010 e-mail from -- the one I want
4 to focus on is from Angela Parlato at
5 Walgreens.
6 Do you see that?
7 A. To Angela Parlato, yes, ma'am.
8 Q. And this is WAGFLDEA00000459,
9 which you have cited at note 499 of your
10 report, correct, sir?
11 A. Yes.
12 Q. You can see from Ms. Parlato's
13 signature line that she was a Pharm.D., a
14 registered pharmacist --
15 A. Yes.
16 Q. -- and pharmacy manager,
17 correct, sir?
18 A. Yes.
19 Q. You see that she -- it says
20 that she's the pharmacy manager at the
21 bottom? It's at the bottom of the back page.
22 A. It does say that on the back
23 page.
24 Q. She's e-mailing a pharmacy
25 supervisor in Orlando, Florida, correct, sir?

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1 A. Yes.
2 Q. Do you understand that there
3 was a known issue with pill mills in Florida
4 in this time frame, summer 2010?
5 A. Yes, I do.
6 Q. And Ms. Parlato is writing to
7 the pharmacy supervisor about concerns she
8 has had at her pharmacy, correct?
9 A. Yes, she is.
10 Q. All right. I'm going to focus
11 your attention on the second paragraph of
12 Ms. Parlato's e-mail. I'm just going to read
13 it so we're on the same page.
14 Ms. Parlato writes: Brandon
15 and I have agreed that we will only fill if
16 they produce a driver's license matching name
17 on Rx, write down the diagnosis of patient on
18 Rx, and verify Rx with doctor office. Every
19 week I increase my order of oxy 30 and every
20 week I run out as more and more people are
21 coming. I have caught a total of seven
22 fraudulent Rx's from three patients in the
23 last two months. The last patient was
24 arrested and had a bail set at \$50,000.
25 I have called the Ocala police,

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1 the Marion County Sheriff's Office here, as
2 well as the Broward County Sheriff's Office,
3 the DEA, and to be quite honest, no one
4 really seems to take my reports that
5 seriously, except for this last week when the
6 fake Rx man was arrested. They promise to
7 come and interview me and look at the data I
8 have collected, but thus far, no follow-up.
9 The bottom line is I want to
10 make sure I'm covering myself so no one
11 thinks I or Brandon are doing anything
12 unethical or illegal.
13 Did I read all that correctly?
14 A. You did.
15 Q. The pharmacist here is telling
16 her supervisor that she's checking
17 prescriptions that have red flags. Would you
18 agree with that?
19 A. I do.
20 Q. She says that she's only
21 filling prescriptions for patients who
22 produce a driver's license matching the name
23 on the prescription?
24 A. Yes, ma'am.
25 Q. She says she's verifying

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1 prescriptions with doctors' offices?
2 A. Yes, ma'am.
3 Q. She says she's caught a total
4 of seven fraudulent prescriptions from three
5 patients in the past two months, correct?
6 A. She does.
7 Q. She doesn't say she's filling
8 those fraudulent prescriptions, right?
9 A. She does not.
10 Q. From this e-mail, it's pretty
11 clear she's not filling the fraudulent
12 prescriptions, right?
13 A. You could draw that conclusion
14 from this e-mail.
15 Q. She says she's called the Ocala
16 police, the Marion County Sheriff's Office,
17 and Broward County Sheriff's Office and the
18 DEA, correct, sir?
19 A. Yes.
20 Q. She's calling law enforcement
21 whenever she sees something wrong, at least
22 by her own description, correct, sir?
23 A. She is.
24 Q. She says no one is taking her
25 reports all that seriously?

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1 A. Yes, ma'am.
2 Q. And she wants to make sure
3 there's not something else that she should be
4 doing, correct?
5 A. I think she's reaching out for
6 that type of advice, yes, ma'am.
7 Q. When you worked at the DEA,
8 isn't this exactly the type of thing that you
9 wanted pharmacists to be doing?
10 A. To call me in this manner?
11 Yes, ma'am.
12 Q. This is not the type of
13 pharmacist you would accuse of not doing her
14 job, is it, sir?
15 MR. FULLER: Object to form,
16 lack of information.
17 A. I'm sorry, I'm thinking a
18 second about that Touhy. I have that Touhy
19 issue in mind.
20 BY MS. SWIFT:
21 Q. I'm not asking based on any
22 investigation you worked on at the DEA. I'm
23 basing on this --
24 A. No, I'd like to --
25 Q. -- this document that was

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1 produced in litigation, whether this is the
2 kind of pharmacist you would say she's not
3 doing her job.
4 A. I would not say she's not doing
5 her job.
6 Q. You don't have an opinion in
7 this case that there was anything else this
8 pharmacist should have been doing, correct,
9 sir?
10 MR. FULLER: Object to form.
11 A. Well, if I would -- if I would
12 have received this information that's
13 described in here and she called me and I was
14 working as a DEA investigation -- DEA
15 investigator, I would probably have a little
16 more of an extensive conversation with her in
17 regards to the content of the prescriptions,
18 confirm that she's actually doing these
19 things that she's doing.
20 I may have some questions for
21 her in regards to the doctors and the
22 location, how far the patients are traveling
23 within Florida. I might give her a little --
24 I might ask some questions that might end up
25 being guidance, and I'm not so sure that --

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1 I'm a little concerned about the statement
2 that no one did anything. That's troublesome
3 to me.
4 BY MS. SWIFT:
5 Q. She found it troublesome too,
6 didn't she, sir, at least based on the
7 e-mail?
8 A. Yeah. Yes, you know, anytime
9 diversion is not acted upon, I find it
10 troubling. So I probably would have did a
11 little more than what's in here, but that's
12 just me personally.
13 There's -- when I used this,
14 there was other things that troubled me in
15 this e-mail, but I'm going to answer your
16 question just specific to that. Yeah, I
17 don't think she did anything wrong.
18 But I think she didn't get
19 sufficient guidance that potentially what she
20 was doing wasn't enough.
21 Q. Wasn't for lack of trying,
22 though, correct, sir?
23 A. Understood. But just reading
24 what she wrote, there is still a potential
25 that filling those prescriptions with the

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1 situation that was going on in Florida, which
2 she obviously has knowledge of and the people
3 coming from Ohio, I'm a little concerned that
4 maybe she could have probably done a little
5 more as a pharmacist.
6 Q. You don't offer any opinions in
7 your report about any of that, correct, sir?
8 A. About her actions?
9 Q. Correct.
10 MR. FULLER: Object to form.
11 A. No, I do not.
12 BY MS. SWIFT:
13 Q. Let's take a look at the next
14 paragraph of Ms. Parlato's e-mail. Are you
15 with me?
16 A. I am.
17 Q. It says: This past week, the
18 warehouse called me to inquire about the
19 growing orders of oxy 30 I have been placing
20 and said that it is a red flag of sorts when
21 a store orders more than 30 bottles per
22 order. I ordered 55 this week and have no
23 doubt I will sell them all before my next
24 order comes in.
25 Did I read that correctly?

<p style="text-align: right;">Page 528</p> <p>1 A. You did.</p> <p>2 Q. Do you think that the DC</p> <p>3 personnel was doing something wrong here</p> <p>4 based on this one paragraph?</p> <p>5 A. Well, I don't have complete</p> <p>6 information to make a real firm judgment, but</p> <p>7 I would say the tone of this and the content</p> <p>8 would make me question about how quickly the</p> <p>9 orders increased or the escalation and why it</p> <p>10 got to such a problem in the previous -- the</p> <p>11 paragraph above it and now is being called</p> <p>12 and why it maybe should have been triggered</p> <p>13 earlier.</p> <p>14 Q. But you don't know about any</p> <p>15 other communications that this person at the</p> <p>16 distribution center may have had with</p> <p>17 Ms. Parlato, correct?</p> <p>18 A. No, I don't, but I'm just</p> <p>19 answering your question based on just that</p> <p>20 paragraph.</p> <p>21 Q. The distribution center person</p> <p>22 who Ms. Parlato spoke with is also checking</p> <p>23 on red flags, correct, sir? That's what it</p> <p>24 says in the paragraph?</p> <p>25 A. Well, that's the part that</p>	<p style="text-align: right;">Page 530</p> <p>1 Ms. Parlato's pharmacy other than reading</p> <p>2 this e-mail, correct, sir?</p> <p>3 A. As we sit here today, no,</p> <p>4 ma'am.</p> <p>5 Q. You haven't done an ARCOS</p> <p>6 analysis of the volume of oxy shipped to this</p> <p>7 pharmacy, anything like that?</p> <p>8 A. I have not.</p> <p>9 Q. And you have no opinion on how</p> <p>10 many of the prescriptions that this</p> <p>11 pharmacist saw were legitimate, correct?</p> <p>12 MR. FULLER: Form.</p> <p>13 A. No, but I don't have access to</p> <p>14 the information to be able to form that</p> <p>15 opinion.</p> <p>16 BY MS. SWIFT:</p> <p>17 Q. Is it your opinion that the</p> <p>18 distribution center should have cut and</p> <p>19 reported all orders above 30 bottles of</p> <p>20 oxycodone?</p> <p>21 MR. FULLER: Form, improper</p> <p>22 hypothetical.</p> <p>23 A. Well, that kind of goes to the</p> <p>24 heart of the failure of due diligence,</p> <p>25 because -- and I'm just speaking based on</p>
<p style="text-align: right;">Page 529</p> <p>1 concerns me. I'm not so sure it's a red flag</p> <p>2 more than a suspicious order.</p> <p>3 Q. Okay. You don't know what else</p> <p>4 the distribution center did to investigate</p> <p>5 this order, correct, sir?</p> <p>6 A. I do not, but it's concerning</p> <p>7 to me because in a suspicious order system,</p> <p>8 there are no -- I've never seen the term "red</p> <p>9 flag." The pharmacy conduct would be --</p> <p>10 those are red flags, so I -- that's why</p> <p>11 there's some concern with that paragraph.</p> <p>12 Q. You don't know whether this</p> <p>13 particular order that is being discussed in</p> <p>14 Ms. Parlato's e-mail ever shipped, correct,</p> <p>15 sir?</p> <p>16 A. Well, this doesn't say whether</p> <p>17 or not it shipped, but that paragraph would</p> <p>18 lead you to the assumption that she believes</p> <p>19 it's going to be shipped and she could buy</p> <p>20 more.</p> <p>21 Q. You didn't do anything to</p> <p>22 confirm that?</p> <p>23 A. I did not.</p> <p>24 Q. And you haven't done any</p> <p>25 further inquiry into what was going on at</p>	<p style="text-align: right;">Page 531</p> <p>1 this and your term of using 30 bottles.</p> <p>2 I don't know what due diligence</p> <p>3 existed that they would establish a threshold</p> <p>4 or what pattern of purchase previously, so</p> <p>5 just to give me an arbitrary number, I can't</p> <p>6 make comment on that.</p> <p>7 BY MS. SWIFT:</p> <p>8 Q. Okay.</p> <p>9 A. But that's the essential</p> <p>10 purpose of the due diligence, is to be able</p> <p>11 to know what the usual order is.</p> <p>12 Q. But you don't have an opinion</p> <p>13 that this particular distribution center</p> <p>14 should have done something to cut off</p> <p>15 shipments beyond 30 bottles or anything like</p> <p>16 that?</p> <p>17 MR. FULLER: Object to form,</p> <p>18 insufficient evidence or facts.</p> <p>19 A. I don't have an opinion because</p> <p>20 I don't have the due diligence or records to</p> <p>21 make an opinion on that right now.</p> <p>22 BY MS. SWIFT:</p> <p>23 Q. All right. Turn to page 121,</p> <p>24 please. Getting close.</p> <p>25 The top of page 121 says --</p>

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1 I'll wait until you're there.
2 A. Go ahead.
3 Q. The top of page 121 says: The
4 bar graphs identified as Figures 45 to 56 in
5 Schedule II of this report demonstrate a
6 clear escalation of prescription opioids into
7 Cuyahoga County and Summit County by dose,
8 base weight and MME. The massive increase in
9 prescription opioids without a documented
10 basis is indicative of a failure to maintain
11 effective control.
12 Did I read that correctly?
13 A. You did.
14 Q. The charts and figures in
15 Schedule II of your report come from
16 Dr. McCann, the other plaintiffs' expert,
17 correct?
18 A. Yes, ma'am.
19 Q. They come from Appendix 9 of
20 Dr. McCann's report; is that right? You can
21 see that if you look at Schedule II.
22 MR. FULLER: I don't know the
23 answer.
24 A. I don't.
25 ///

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1 BY MS. SWIFT:
2 Q. Oh, you don't have the
3 schedules? Okay.
4 A. I mean I --
5 MR. FULLER: Somewhere.
6 MS. SWIFT: I've got them.
7 THE WITNESS: It will take me a
8 while. I don't want to use your time.
9 MS. SWIFT: I'm going to mark
10 as Exhibit 23 Schedule II to your
11 report.
12 (Whereupon, Deposition Exhibit
13 Rafalski-23, Rafalski Report
14 Schedule II, was marked for
15 identification.)
16 MR. FULLER: Thank you. You
17 said Exhibit 23?
18 MS. SWIFT: Yep.
19 MR. FULLER: Thanks.
20 BY MS. SWIFT:
21 Q. You can see that Schedule II,
22 if you flip through it, these are all charts
23 from Appendix 9 of Dr. McCann's report?
24 A. Yes, ma'am.
25 Q. You didn't include all of

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1 Appendix 9 to Dr. McCann's report, correct?
2 Or do you know?
3 A. No, I don't believe I included
4 all of the results, no, ma'am.
5 Q. Who selected the charts that
6 are included in Schedule II of your report?
7 A. I believe I gave a description
8 of what I wanted the charts to indicate, and
9 they were provided to me.
10 Q. By plaintiffs' lawyers?
11 A. I believe they were forwarded
12 to me electronically. I don't know who gave
13 them to me. So -- but I believe so. I
14 believe they're the ones who would
15 communicate back and forth with Mr. McCann.
16 Q. You have no idea who provided
17 you the charts that you included in the
18 Schedule II?
19 A. I have a reasonable idea that
20 it would be Mr. Elkins, A.J. Elkins, because
21 that's who I dealt with on a regular basis,
22 but I guess I don't want to be literal with
23 like who actually did it. It's like how do
24 you really know anything? So yes,
25 Mr. Elkins.

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1 Q. Mr. Elkins is one of the
2 plaintiffs' lawyers, correct, sir?
3 A. Yes.
4 Q. Did you review all of
5 Appendix 9 to Dr. McCann's report?
6 A. I don't recall if I did or not.
7 Q. You relied on the charts that
8 are in Schedule II of your report,
9 Dr. McCann's charts, to conclude that several
10 of the defendants in this case had a, quote,
11 massive increase or, quote, escalation of
12 opioids distribution, correct?
13 A. Yes, ma'am.
14 Q. The charts in Schedule II show
15 the volume of shipments of opioids over time,
16 correct?
17 A. Yes, ma'am.
18 Q. The charts in Schedule II do
19 not show the results of Dr. McCann's
20 application of the five flagging
21 methodologies to any of those defendants,
22 correct? It just shows volume?
23 A. It shows volume, distribution,
24 as the report indicates.
25 Q. And it doesn't show which of

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1 those orders were flagged as suspicious?
2 A. It does not.
3 Q. Okay. The charts in Schedule
4 II don't say anything about which orders
5 shipped by these defendants were suspicious,
6 correct?
7 A. These charts don't say that,
8 no, ma'am.
9 Q. The charts in Schedule II also
10 do not show distribution of any particular
11 drug to any particular pharmacy, correct,
12 sir?
13 A. Well, as I stated previously,
14 it contains that data but it doesn't
15 specifically show it. I mean, it's built
16 upon those orders to those pharmacies.
17 Q. Right. But if you wanted to
18 know how much oxy was shipped to any
19 particular pharmacy, you could not tell that
20 from your charts in Schedule II?
21 A. That's a correct statement.
22 Q. When did you receive the charts
23 in Schedule II?
24 A. I don't recall.
25 Q. Did you ever speak to

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1 Dr. McCann about the charts in Schedule II?
2 A. I did not.
3 Q. All right. Other than the
4 charts included in Schedule II and the -- I
5 think there are a few pages of your report
6 where you also cite to Appendix 9 of McCann's
7 report.
8 A. Yes.
9 Q. Did you review any other part
10 of Appendix 9 that is not cited in your
11 report or attached in Schedule II?
12 A. I'm sure I reviewed it. I
13 don't have direct recollection of that.
14 Q. I'm going to show you what I'm
15 marking as Exhibit 24. Might be the last
16 one.
17 (Whereupon, Deposition Exhibit
18 Rafalski-24, Excerpt from McCann
19 Appendix 9, was marked for
20 identification.)
21 MR. FULLER: Counsel, I'm going
22 to ask how much more you've got.
23 We've been going two hours.
24 MS. SWIFT: I don't think we've
25 been going quite two hours. I'm

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1 hoping to wrap up at around two hours.
2 MR. FULLER: We've been going
3 two hours.
4 MS. SWIFT: I don't know if I'm
5 going to quite make it. But I'm going
6 to be close.
7 Do you want to take a break,
8 Mr. Rafalski?
9 MR. FULLER: I do. I have to
10 pee. I'm just being honest.
11 THE VIDEOGRAPHER: We're going
12 off the record at 10:19 a.m.
13 (Recess taken, 10:19 a.m. to
14 10:29 a.m.)
15 THE VIDEOGRAPHER: We're back
16 on record, 10:29 a.m.
17 BY MS. SWIFT:
18 Q. Welcome, Mr. Rafalski.
19 A. Thank you.
20 (Interruption by the reporter.)
21 BY MS. SWIFT:
22 Q. I believe that we agreed off
23 the record that you are going to make or your
24 counsel is going to make a copy of your
25 binder that has your report in it and that's

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1 going to be marked as Exhibit 16; is that
2 correct?
3 A. Yeah, it's -- well, it's
4 already marked as Exhibit 16, and I
5 understand that they're going to do that at
6 lunchtime.
7 Q. That sounds great, thank you.
8 Okay. Now, if you would,
9 please, take a look at page 36 of --
10 A. I'm open to 36.
11 Q. -- Exhibit 24. Before I ask
12 you questions about Exhibit 24, I just want
13 to tell you what it is.
14 Exhibit 24 is, if you can
15 believe it, an excerpt of Dr. McCann's
16 Appendix 9.
17 A. I think it's like 900 pages
18 long.
19 Q. Something like that. I think
20 it's actually 3877 pages long.
21 MR. FULLER: It says that at
22 the bottom.
23 BY MS. SWIFT:
24 Q. As with the other appendices
25 from Dr. McCann's report, what we did was to

<p style="text-align: right;">Page 540</p> <p>1 pull out the pages that relate to Walgreens, 2 okay? 3 A. Sure. 4 MR. FULLER: I'm sorry, so this 5 is just all of Walgreens? 6 MS. SWIFT: Yeah, I think so. 7 That's what I was told. 8 MR. FULLER: Okay. 9 BY MS. SWIFT: 10 Q. Did you look at all 3877 pages 11 of Appendix 9 to Dr. McCann's report? 12 A. No. 13 Q. How much of Appendix 9 did you 14 look at? 15 A. I'm not really sure exactly how 16 many, but nowhere near 3,877 pages. I might 17 look at specific charts related to what I 18 cited -- obviously, the ones that I've cited 19 in my report, but I did not review them all. 20 I'm confident of that. 21 Q. Are you confident that you 22 reviewed anything within Appendix 9 that does 23 not appear in your report? 24 A. Yes, I believe I've looked at 25 some of these charts and they're not</p>	<p style="text-align: right;">Page 542</p> <p>1 distribution chart. I hope that makes sense. 2 So there isn't anything in here 3 that would change my opinion. I have not 4 reviewed a chart that changed my opinion, but 5 they're not all commented on in my report. 6 Q. Well, to be fair, though, sir, 7 I believe you testified you didn't review all 8 of Appendix 9. 9 A. That's correct. 10 Q. Okay. 11 A. Of those I reviewed. 12 Q. All right. And just ballpark 13 it for me. Did you review half of the charts 14 in Appendix 9? 15 A. I wouldn't say probably half. 16 Q. 10%? 17 A. I would say 300. 18 Q. So 10%? 19 A. It could be around that or even 20 a little less. That's 387. I would say 21 2- to 300 charts. 22 Q. Okay. Let's take a look at the 23 chart that appears on page 36 of Exhibit 24. 24 This chart is also page 250 of 3,877. 25 Do you see that?</p>
<p style="text-align: right;">Page 541</p> <p>1 commented on in my report. Yes, I'm sure 2 that I did that. 3 Q. Are they not included in your 4 report because they didn't bear on your 5 opinions? 6 MR. FULLER: Object to form. 7 That's not what his testimony was. 8 A. No, I don't think that's an 9 accurate statement. I -- you know, I guess 10 the question was did I look at some of the 11 charts. I did. 12 BY MS. SWIFT: 13 Q. And then the follow-up question 14 was with respect to the parts of Appendix 9 15 that you did not include in your report, is 16 that because they did not bear on your 17 opinions? 18 A. I'm not sure how to answer that 19 because I think all of the charts in here 20 are -- in some way bear on my opinion because 21 they're all cumulative of other charts. So, 22 for example, if I look at just one chart, I 23 don't have a specific opinion of that chart, 24 but I know that that analysis is probably 25 contained or part of a maybe total</p>	<p style="text-align: right;">Page 543</p> <p>1 A. Yes. 2 Q. This chart is a chart for 3 Walgreens Store No. 12444 at 3415 Clark 4 Avenue. 5 Do you see that at the top 6 left? 7 A. I do. 8 Q. The chart shows oxycodone 9 distribution to Walgreens Store No. 12444, 10 correct? 11 A. Yes. 12 Q. And you can see that it 13 purports to show distribution to this 14 Walgreens store at 3415 Clark Avenue from 15 AmerisourceBergen Drug, Cardinal Health and 16 Walgreens' own distribution centers, correct, 17 sir? 18 A. Yes. 19 Q. Did you review this chart in 20 preparing for your report? 21 A. I don't have any recollection 22 if I saw this specific chart. 23 Q. Is it your understanding that 24 this chart is specifically showing 25 distribution of oxycodone to the Walgreens</p>

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1 pharmacy at 3415 Clark Avenue in Cleveland?
2 A. Of oxycodone?
3 Q. Yes.
4 A. The entire family, yes, ma'am.
5 Q. Do you read this chart to be
6 showing the volume of distribution of
7 oxycodone to this Walgreens at 3415 Clark
8 Avenue from 1996 to 2018? Is that what that
9 appears to show?
10 A. It does appear to show that.
11 Q. Do you know whether this chart
12 for the Walgreens at 3415 Clark Avenue leaves
13 out any shipments of oxycodone for any of
14 these time periods?
15 A. I'm not aware if it does.
16 Q. Did you ask anyone about that?
17 A. No, ma'am.
18 Q. Do you know whether all of the
19 data on this chart for the Walgreens at 3415
20 Clark Avenue is related to the Walgreens at
21 3415 Clark Avenue?
22 A. I didn't do this analysis. It
23 was done by Dr. McCann and it was provided to
24 me, and I would take it as being accurate.
25 And that's what it displays. So that's --

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1 that's what it indicates to me.
2 Q. Okay.
3 A. I did nothing independent to
4 verify any of this information. I relied on
5 Dr. McCann's evaluation.
6 Q. To create the charts like the
7 ones that are in your Schedule II and that
8 also appear in Appendix 9, do you understand
9 that Dr. McCann combined data from the DEA's
10 ARCOS database with some of the defendants'
11 own transactional data?
12 Did you know that?
13 A. Yes, I remember reviewing that
14 in a document or somewhere. I don't know the
15 source, but yes, I am aware of that.
16 Q. Do you understand that the
17 Walgreens data that Dr. McCann used covers
18 one time period and the ARCOS data covers
19 another?
20 A. I believe -- I have a
21 recollection that I did read or was advised
22 of that, yes, ma'am.
23 Q. Did you review the computer
24 code underlying Dr. McCann's charts in his
25 report?

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1 A. I did not.
2 Q. Do you know that there are
3 other experts in this litigation who disagree
4 with many of the things presented in
5 Dr. McCann's report?
6 A. I'm not aware of that.
7 Q. Have you had a chance to look
8 at any of the other expert reports produced
9 by the defendants in this case?
10 A. Can I get a -- ask a
11 clarification?
12 Q. Sure.
13 A. Are you asking whether they're
14 available to me? Because I don't know if
15 they were provided. I have not done that,
16 but I don't know if they may be accessible to
17 me. But I have not reviewed them.
18 Q. Okay. One more set of charts.
19 Sorry.
20 A. That's all right.
21 (Whereupon, Deposition Exhibit
22 Rafalski-25, Excerpt from McCann
23 Appendix 11, was marked for
24 identification.)
25 THE WITNESS: Are we done with

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1 this one?
2 MS. SWIFT: Yep.
3 (Comments off the stenographic
4 record.)
5 BY MS. SWIFT:
6 Q. I'm marking as Exhibit 25 an
7 excerpt of McCann's Appendix 11, and like
8 with the others today, what we've done is
9 pulled out the pages that relate to
10 Walgreens, okay?
11 A. Okay.
12 Q. Have you ever seen the charts
13 that appear in Exhibit 25?
14 A. I believe I looked at these
15 because they were part of the methodology
16 analysis.
17 Q. Who shared them with you?
18 A. I believe Mr. Elkins would have
19 provided them to me.
20 Q. The plaintiffs' lawyer,
21 Mr. Elkins?
22 A. Yes.
23 Q. When did Mr. Elkins share the
24 charts in Exhibit 25 with you?
25 A. I don't recall.

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1 Q. You didn't cite or attach any
2 of these charts to your report, correct, sir?
3 A. No, I don't believe I did.
4 Q. You've never talked to
5 Dr. McCann about any of the charts in his
6 report; am I right about that?
7 A. That's correct.
8 Q. Okay. All right. You can set
9 those aside. That's all I was going to do
10 with that one.
11 Turn, if you would, please, to
12 page 115 of your report. Page 115 is within
13 the Walgreens section and talks about an
14 investigation of the Jupiter distribution
15 center in Florida, correct, sir?
16 A. It does at the bottom of the
17 page.
18 Q. You didn't have any personal
19 involvement in the Jupiter, Florida
20 investigation of Walgreens, correct?
21 A. No, ma'am, I don't believe so.
22 Q. To the extent that you have
23 opinions about the Jupiter, Florida
24 investigation, you're relying entirely on the
25 Order to Show Cause and related documents

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1 attached to Walgreens' 2013 settlement
2 agreement with the DEA -- is that right --
3 cited in note 493?
4 A. Yes, ma'am.
5 Q. Okay. Did you -- in preparing
6 for your -- to write your report, did you
7 review any of the documents showing
8 Walgreens' efforts to cooperate with Florida
9 DEA and local law enforcement in 2010 and
10 2011?
11 Do you remember anything like
12 that?
13 A. I don't remember reviewing any
14 records or communications in regards to that,
15 no, ma'am.
16 Q. In preparing your report, did
17 you review any of the documents produced by
18 the plaintiffs, Cuyahoga and Summit County,
19 showing Walgreens' pharmacists notifying
20 local law enforcement when they suspected
21 diversion?
22 A. No, ma'am.
23 Q. Turn, if you would, please, to
24 page 118. I'll direct your attention to the
25 last paragraph on the page that starts

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1 "Despite having raised."
2 Do you see that?
3 A. Yes, ma'am.
4 Q. This is still in the section
5 talking about what you learned from the Order
6 to Show Cause in the Jupiter matter, correct?
7 A. Yes.
8 Q. And you talk in this last
9 paragraph on 118 about Store No. 3836.
10 Do you see that?
11 A. Yes.
12 Q. That's one of the stores that's
13 discussed in the Florida Order to Show Cause?
14 A. Okay.
15 Q. Do you recall that that's the
16 case?
17 A. Do you have the memorandum of
18 agreement I could review? Or I could get it
19 out.
20 Q. That's okay. I'll withdraw the
21 question.
22 The statements in that last
23 paragraph on Store No. 3836 about the volume
24 of shipments of oxycodone to that pharmacy,
25 are you relying exclusively on the documents

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1 cited in notes 509 and 510 for those numbers?
2 MR. FULLER: Form, same
3 objection as earlier.
4 A. You're talking about the
5 statements in the last paragraph?
6 BY MS. SWIFT:
7 Q. Correct, and in particular the
8 statements about the volume of oxycodone
9 shipments to that store.
10 MR. FULLER: Same objection.
11 A. No, I believe it's also in
12 regards to some deposition information and
13 some other documents.
14 BY MS. SWIFT:
15 Q. You're talking about stuff
16 that's cited in your report though?
17 A. In a general nature, yes,
18 ma'am. It's cited.
19 Q. Just not cited here on the page
20 where you're talking about Store 3836?
21 A. Yes. Yes.
22 Q. You didn't do an ARCOS analysis
23 or request an ARCOS analysis to verify the
24 volume numbers with respect to Store 3836,
25 correct, sir?

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1 A. As I sit here today, I did not
2 do that.
3 Q. Okay. Turn to page --
4 A. I'm -- there's probably a chart
5 in here related to that that Dr. McCann --
6 but it would be an overall volume chart.
7 Q. But you don't know one way or
8 the other?
9 A. Well, I'm pretty confident
10 there is one there.
11 Q. Okay.
12 A. But I don't positively know.
13 Q. Turn to page 121, please. The
14 second full paragraph on page 121 talks about
15 the Florida migration phenomenon.
16 Do you see that?
17 A. Yes, ma'am.
18 Q. And that's the idea that
19 prescription opioids dispensed in Florida
20 were then transported north to other states;
21 is that right?
22 A. Yes, ma'am.
23 Q. Do you rely on anything other
24 than the documents cited in notes 518, '19
25 and '20 to support your statements that

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1 Walgreens knew about the Florida migration
2 theory?
3 MR. FULLER: Same objection and
4 basis as earlier.
5 MS. SWIFT: Yes or no, please.
6 THE WITNESS: Okay. I'm
7 thinking about it.
8 A. I think I also relied on my
9 experience and my knowledge of what was going
10 on at this time period and the media coverage
11 and the newspaper coverage in Florida. So I
12 would say that that would also have an impact
13 on that decision.
14 BY MS. SWIFT:
15 Q. And my question was --
16 A. But I can't cite you a specific
17 article or specific news show, but it was
18 pretty common in the media at the time.
19 Q. And my question was
20 specifically with respect to Walgreens'
21 knowledge.
22 Do you rely on anything other
23 than the documents cited in notes 518, '19
24 and '20 to support your statements that
25 Walgreens knew about the Florida migration

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1 theory?
2 MR. FULLER: Same objection and
3 basis.
4 A. Same answer. I think by this
5 time period, everybody knew there was a
6 problem in Florida.
7 BY MS. SWIFT:
8 Q. Did you check the documents
9 that you cite here to see if any of them
10 actually talk about pills migrating from a
11 Florida Walgreens to people in Ohio?
12 A. I checked the documents. I
13 don't have a direct recollection if it said
14 out of state or Ohio.
15 Q. You would agree with me, sir,
16 that based on everything you've reviewed,
17 Walgreens only ever distributed controlled
18 substances to its own pharmacies, correct?
19 A. I'm not aware of any records
20 which have indicated they distribute anything
21 to other than their own registrants, but I
22 didn't look at some transactions where that
23 may occur, for example, destruction --
24 destruction of drugs may have went to a
25 reverse distributor. So in my experience,

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1 there would be some other types of
2 distributions --
3 Q. You're not offering --
4 A. -- but not -- but I'm not
5 disagreeing with the question. Generally,
6 yes, would be the question, but I'm leaving
7 open that there's other distributions that
8 may have occurred.
9 Q. You're not offering any
10 opinions in this case about suspicious orders
11 connected to destruction of drugs and reverse
12 distribution, correct, sir?
13 A. No, I don't think -- not to be
14 argumentative, I don't think your question
15 was in regards to suspicious orders. It was
16 just distribution.
17 Q. And then I asked another
18 question.
19 A. Oh, I was still answering the
20 first question.
21 Q. Understood.
22 You're not offering any
23 opinions about orders that were shipped by
24 reverse distributors, correct?
25 A. No, I'm not.

<p style="text-align: right;">Page 556</p> <p>1 Q. Okay. You haven't offered an 2 opinion in this case about how long it was 3 supposed to take for a registrant to get a 4 new suspicious order monitoring system up and 5 running, have you, sir?</p> <p>6 A. I think I've made a lot of 7 comments within my report. I don't think 8 there's a provable time period to not have 9 one.</p> <p>10 Q. We talked --</p> <p>11 A. It's -- it's a requirement of 12 the registration to have a suspicious order 13 monitoring system, so there's no time period 14 where I'd say they -- I would ever approve 15 where they just couldn't have one.</p> <p>16 Q. But you didn't offer an opinion 17 about how long it's supposed to take to get a 18 suspicious order monitoring system up and 19 running?</p> <p>20 A. No, because that hypothetically 21 doesn't exist. They should have one. They 22 should have one upon registration. There -- 23 I would never -- or the DEA -- or speaking 24 for myself, I would never approve a 25 registrant that didn't have one in place.</p>	<p style="text-align: right;">Page 558</p> <p>1 system, which I don't think was adequate. If 2 they were developing a new system, if they 3 were beta testing it at the same time, I 4 don't think there would be ever a period of 5 time where, whether it's an approved or not 6 suspicious order system, there was one in 7 place.</p> <p>8 I don't think I alleged that 9 there never was one in place, and I'm not 10 saying that they should abandon one and not 11 test the other, but certainly, to put one in 12 place that's not beta tested and to work 13 diligently to verify whether it's operating 14 properly would be better than just not to put 15 it in place.</p> <p>16 Q. You understand that Walgreens 17 had a system, the E(3) system, and was 18 reporting based on that system for a number 19 of years, correct?</p> <p>20 A. I do, but as my opinion says, I 21 don't think that that was a sufficient 22 suspicious order system.</p> <p>23 Q. You don't like that system, but 24 you understand that Walgreens had that 25 suspicious order monitoring system in place?</p>
<p style="text-align: right;">Page 557</p> <p>1 Q. We talked earlier about the 2 fact that Walgreens was reporting for a 3 certain time period using the E(3) formula 4 that's found in the Chemical Handler's 5 Manual.</p> <p>6 Do you remember that testimony?</p> <p>7 A. Yes, I do.</p> <p>8 Q. And then Walgreens switched 9 over at a certain point to using a new, 10 different type of suspicious order monitoring 11 system, correct, sir?</p> <p>12 A. Yes, ma'am.</p> <p>13 Q. You don't offer an opinion 14 about -- well, strike that.</p> <p>15 Is it your opinion that 16 Walgreens was required to stop reporting 17 using the E(3) formula and start reporting 18 based on the new suspicious order monitoring 19 system as soon as that algorithm was 20 developed, like before any testing had 21 happened or anything like that?</p> <p>22 A. Well, typically, my experience 23 would indicate that if there's a system in 24 place, I'm not saying I'm approving that 25 particular system, the E(3) suspicious order</p>	<p style="text-align: right;">Page 559</p> <p>1 A. They had that system in place. 2 And it's not what I like or not; it's what 3 meets the regulatory requirements.</p> <p>4 Q. You understand that Walgreens 5 had the E(3) system in place and continued 6 reporting based on that system while it 7 developed its new suspicious order monitoring 8 system, correct?</p> <p>9 A. I believe that possibly 10 occurred, yes.</p> <p>11 Q. At page 128 of your report, you 12 talk about a number of what you refer to as 13 either gaps or loopholes in the Walgreens 14 suspicious order monitoring system, correct?</p> <p>15 A. Yes.</p> <p>16 Q. You did not perform an analysis 17 to determine whether any of these so-called 18 gaps or loopholes in the Walgreens system 19 actually led to a suspicious order, correct, 20 sir?</p> <p>21 A. So is your question in regards 22 to a specific order?</p> <p>23 Q. Yes.</p> <p>24 A. I did not do an analysis of a 25 specific order, but the failure to monitor</p>

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1 distributions from an outside source, an
2 outside distributor and account that into
3 your system, that was what the -- what some
4 of the gaps and loopholes were in the system,
5 I believe.
6 Q. But the answer to my question
7 is that you did not do an analysis of any
8 specific order to see whether any of the gaps
9 or loopholes you identified in the Walgreens
10 systems actually led to that suspicious
11 order?
12 A. As of today, I did not do that
13 analysis.
14 Q. At page 132 of your report,
15 right before Section 3, do you see the -- are
16 you with me?
17 A. I am.
18 Q. You agree with me that
19 Walgreens' last Schedule II shipment as a
20 distributor to Cuyahoga and/or Summit County
21 was on March 4th, 2013?
22 A. As cited in the footnote, in
23 review of the ARCOS, I believe, but as cited
24 in the footnote excluding the codeine drug
25 code 9050.

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1 Q. You don't have any opinions in
2 your report about Walgreens' suspicious order
3 monitoring program after Walgreens stopped
4 distributing controlled substances, correct,
5 sir?
6 A. I don't believe I offer an
7 opinion after that point.
8 MS. SWIFT: All right. I
9 have -- I'm not going to ask you any
10 other questions at this time, but as
11 my colleagues have done, I'm going to
12 reserve the right to come back and ask
13 you additional questions later, both
14 because we have not had time to ask
15 you everything we needed to ask you
16 and because I understand from your
17 testimony today and yesterday that you
18 may be supplementing your opinions at
19 some later point. We reserve the
20 right to ask you about those questions
21 later. Thank you very much, sir.
22 THE WITNESS: Thank you very
23 much. If my attorney approves, I'd be
24 more than happy to sit down again with
25 you.

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1 THE VIDEOGRAPHER: Off the
2 record, 10:53 a.m.
3 (Recess taken, 10:53 a.m. to
4 10:56 a.m.)
5 THE VIDEOGRAPHER: Back on the
6 record at 10:56 a.m.
7 EXAMINATION
8 BY MR. BUSH:
9 Q. So, good morning, Mr. Rafalski.
10 I'm Graeme Bush, and I'm representing CVS in
11 this litigation.
12 A. Good morning, Mr. Bush.
13 Q. So I want to ask a couple of
14 general questions to just get a few
15 housekeeping matters out of the way.
16 First of all, are the opinions
17 that are expressed in your report the same
18 opinions that you hold today?
19 A. They are.
20 Q. And are there any additional
21 opinions that you've developed since your
22 report was delivered to us? And actually,
23 let me limit that because I think you've
24 already been asked that question generally.
25 Are there any additional

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1 opinions relating to CVS that you've reached
2 since the time that your report was
3 delivered?
4 A. No, sir.
5 Q. And have you reviewed -- your
6 report refers to a number of documents and
7 depositions in footnotes throughout the
8 report.
9 Is there any material that is
10 not -- that is not referred to in the report
11 that you've reviewed or come into possession
12 of that bears on your opinions to CVS since
13 the time that your report was provided to us?
14 A. No, sir.
15 Q. Okay. Now, you testified
16 yesterday about the process of drafting the
17 report?
18 A. Yes.
19 Q. And in part of your testimony
20 you referred to the interaction between you
21 and the attorneys for plaintiffs.
22 A. Yes, sir.
23 Q. Did you receive any input
24 from -- actually, let me withdraw that
25 question.

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1 Did you receive drafts of the
 2 section of your report relating to CVS from
 3 any of plaintiffs' attorneys?
 4 A. I'm not sure I would call it a
 5 draft of my report. I would receive some
 6 analysis of some documents or reference me to
 7 certain documents, but I'm not so sure I
 8 would call it a draft.
 9 There were some communications
 10 in regards to the -- I recall in the CVS,
 11 there was the period of time where the 1.5
 12 and 6.5 [sic] and there was some, you know,
 13 brief summaries of that which I, in turn,
 14 redrafted into my report. So I received
 15 things of that nature. But it's not like I
 16 took apart and just pasted it in there. This
 17 was all my report.
 18 Q. From whom did you receive that
 19 kind of work product?
 20 A. That communication either came
 21 through Mr. Fuller or Mr. Elkins, so
 22 sometimes I don't know who the original
 23 author was.
 24 Q. And were some parts of what you
 25 received from Mr. Elkins or Mr. Fuller

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1 describing -- for example, you just gave the
 2 example of the 1.5/1.6 scoring issue -- I'm
 3 sorry, 1.5/.65 scoring issue.
 4 Did you incorporate pieces of
 5 that into your report?
 6 A. I can't say that if there was a
 7 sentence in that part that I totally agreed
 8 with and it was verified by the record, then
 9 it's a possibility that would have occurred.
 10 But again, it's my report.
 11 Q. How about if there was a whole
 12 paragraph that described what happened with
 13 the 1.5/.65 scoring issue?
 14 A. I don't recall that occurring
 15 in the CVS. I'm not going to say it didn't
 16 happen, but again, if it did, I would read it
 17 and make sure that that was consistent with
 18 what the document said.
 19 It wasn't provided -- it wasn't
 20 my opinions that were provided to me, but if
 21 there was an analysis of a certain document
 22 and I found it to be accurate, I would not
 23 change that.
 24 Q. Did -- I take it you received
 25 this kind of input in the form of some

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1 writing or another.
 2 How did you receive it?
 3 A. Yes.
 4 Q. By e-mail?
 5 A. No, not by e-mail. It would
 6 be -- I would do my report in a Google Drive,
 7 so it would be a redlined or if something got
 8 inserted, you know, I would know that it
 9 wasn't part of my original report. And I may
 10 get a notification that it's been updated,
 11 but I pretty much was looking at it all the
 12 time, so...
 13 Q. You testified yesterday about
 14 how much time you spent on each of the
 15 defendants in preparing your opinion with
 16 respect to them.
 17 Do you remember that general
 18 subject matter?
 19 A. I remember I kind of gave a
 20 general answer to that time.
 21 Q. And you said, I think in
 22 response to questions from Mr. Pyser, that
 23 you estimated it was maybe 50 or 60 hours per
 24 distributor and you made a distinction
 25 between distributors and some other of the

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1 defendants.
 2 Do you recall that?
 3 A. Generally, yes. I don't know
 4 if that was exactly what I said, but
 5 generally, I did do the distinction.
 6 Q. And do you include -- well, let
 7 me just ask it this way: How much time do
 8 you estimate you spent on CVS?
 9 A. I don't really have a specific
 10 hour I could give you. If I broke them up in
 11 50 and 60, I would say in just a general
 12 statement, I probably spent more time on CVS
 13 than I did on some of the other distributors.
 14 Q. Okay.
 15 A. It's just a generalized. If
 16 you were to say did you spend more or less
 17 time on CVS, I would say more. I spent a lot
 18 of time trying to understand the Buzzeo
 19 complicated suspicious order system. I spent
 20 a considerable time trying to work on that,
 21 and then the .15/.65 [sic] scoring, a lot of
 22 review of documents there.
 23 So probably more than -- it
 24 would be 60 -- at the upper range of what I
 25 spent on all the other distributors.

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1 Q. All right. Thank you.
 2 During your time at DEA, did
 3 you have any personal involvement with CVS?
 4 A. So in response to your
 5 question, when you say "personal
 6 involvement," I'm sure that on several
 7 occasions I would have went into a
 8 CVS Pharmacy, and on a professional basis
 9 first --
 10 Q. Okay.
 11 A. -- and a personal basis, but --
 12 and pulled documents related to
 13 investigations I was conducting, if I was
 14 doing -- I know for sure in some of the
 15 physicians I investigated, I may go in and
 16 pull original prescriptions, I may ask for
 17 profiling reports.
 18 So, yes, I would have had
 19 contact with CVS Pharmacies.
 20 Q. Did you have -- were you
 21 involved in any inspection of a CVS
 22 distribution center?
 23 A. I was not.
 24 Q. Were you involved in any other
 25 kind of enforcement action with respect to a

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1 CVS distribution center?
 2 A. Not that I can recall at this
 3 time, no, sir.
 4 Q. Would it be accurate to say
 5 that you are not going to be able to come to
 6 the trial and testify about any personal
 7 experiences you've had as a DEA agent with
 8 regard to investigations of CVS? And I'm not
 9 talking about Touhy here, I'm just talking
 10 about you didn't have any personal experience
 11 so even if --
 12 A. As I sit here today, I don't
 13 have any recollection of anything that would
 14 change my opinion or that I could add to my
 15 opinion based on my employment and
 16 investigations or information.
 17 Could I just make one minor
 18 correction? So in -- not that it's a huge
 19 deal. I'm not an agent, because that's --
 20 I'm a diversion investigator. Not to be
 21 critical of you calling me --
 22 Q. No, sure.
 23 A. Because I get called that all
 24 the time.
 25 Q. Fair enough. Fair enough.

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1 A. But it's a different -- I know
 2 law enforcement --
 3 Q. But your answer is the same,
 4 correct?
 5 A. My answer is the same, but I
 6 couldn't come as an agent to do it either
 7 because I'm too old to do that, but I
 8 appreciate it.
 9 Q. If you take a look at page 41
 10 of your opinion, Ms. Swift asked you some
 11 questions about the way those numbers were
 12 put together and your involvement of them --
 13 with them?
 14 Do you recall that?
 15 A. Yes.
 16 Q. And at some point she started
 17 to ask you questions that were focused on
 18 Walgreens, but would it be true that your
 19 answers would be the same if I asked you the
 20 same questions about CVS, you put the numbers
 21 together the same way for CVS as you did for
 22 Walgreens?
 23 MR. FULLER: Form.
 24 A. Yes. If you were to ask the
 25 questions the same way -- I can't remember

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1 her name.
 2 BY MR. BUSH:
 3 Q. Ms. Swift.
 4 MR. FULLER: Ms. Swift. But he
 5 has to speak in her same voice too.
 6 A. Then my answers would be the
 7 same, except I would insert the CVS data.
 8 BY MR. BUSH:
 9 Q. Okay.
 10 A. And of course, CVS didn't have
 11 the Schedule II, so we wouldn't discuss that.
 12 That would be zero.
 13 Q. Right. Now, you also -- I want
 14 to just touch briefly on the methods. I
 15 think others have covered most of what I
 16 would want to ask, but there are a couple of
 17 things I want to ask about the five
 18 methodologies.
 19 A. Yes.
 20 Q. And I think you clarified one
 21 thing that was unclear to me until this
 22 morning, that the five methodologies were
 23 used by -- as you understood it, in some
 24 form, by other registrants, except for one,
 25 which was the, what, two times national

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1 average?
 2 A. Two times. It was actually
 3 used by another registrant, but it was a
 4 manufacturer, so -- so I'm aware it's -- it
 5 had been used in the industry, but not used
 6 in the group that I'd formed an opinion on.
 7 Q. All right. And the Method A, I
 8 think is the way you've labeled it in your
 9 report, which is the six-month trailing
 10 average?
 11 A. Yes.
 12 Q. Sometimes referred to as the
 13 Masters method here?
 14 A. Yes.
 15 Q. That's the one that you're
 16 endorsing as a -- for the purposes that
 17 you've used it in your opinion; is that
 18 right?
 19 A. Well, I think that's fairly
 20 accurate, but I think I pointed out that it's
 21 not just my endorsement; it's the fact that
 22 it's been litigated and went up to the D.C.
 23 Court and there was opinion published on
 24 that.
 25 Q. And that methodology did not

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1 have as a part of it that if you missed an
 2 order that should have been flagged,
 3 everything after that would be flagged?
 4 MR. FULLER: Object to form,
 5 misstates his testimony.
 6 A. I don't understand the
 7 question.
 8 BY MR. BUSH:
 9 Q. Well, the way you have applied
 10 all of these methodologies -- but let's focus
 11 on the Masters methodology for a moment.
 12 A. Sure.
 13 Q. If an order that should have
 14 been flagged as a suspicious order is missed,
 15 you're saying every order after that is a
 16 suspicious order; that's the way your
 17 methodology is applied here, right?
 18 MR. FULLER: Form, misstates
 19 his report.
 20 A. I don't say "missed." I say if
 21 a trigger -- if the Masters algorithm is
 22 applied and a suspicious order report is
 23 triggered or identified, and then there's no
 24 due diligence subsequent to that, then all
 25 orders after that point are flagged and

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1 reported by Dr. McCann.
 2 BY MR. BUSH:
 3 Q. And that feature of the way you
 4 apply Masters is not a feature of the actual
 5 Masters system. That's something you've
 6 added to it, right?
 7 A. That's a confusing question
 8 because it would never be part of the Masters
 9 system.
 10 Q. Okay. So it's not part of the
 11 Masters system and you've added it because of
 12 your interpretation of the way the law would
 13 work, right?
 14 A. The regulation would work and
 15 the law, the maintenance of effective
 16 controls and the Court's opinion and the
 17 training and distributor briefings. Yes, all
 18 of those things.
 19 Q. Is there anything in a
 20 distributor briefing that says that if a
 21 trigger is -- how do you put it, a trigger is
 22 missed? What do you -- what is it that
 23 triggers everything afterwards flagging?
 24 A. So the trigger isn't -- if I
 25 understand your question, it's not just the

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1 trigger. The trigger or the threshold that
 2 gets breached which creates the suspicious
 3 order. That's what the Masters six months
 4 trailing. There's an order that goes back to
 5 previous six months greater than the highest
 6 monthly order.
 7 Q. Right.
 8 A. That triggers a stop for a
 9 suspicious order. Then subsequent to that
 10 suspicious order, before it's shipped, there
 11 should be sufficient due diligence to dispel
 12 the suspicion.
 13 I'm saying if the due diligence
 14 doesn't occur, based on my training, guidance
 15 and experience, everything subsequent to that
 16 also becomes a suspicious order, and that's
 17 reported by Dr. McCann.
 18 Q. Right. And is that in -- or
 19 was that part of any distributor briefing,
 20 that particular feature of how you look at
 21 the world here?
 22 A. I don't know if it's just how I
 23 look at the world, but I believe every
 24 distributor briefing, there is a comment on
 25 that when you identify a suspicious order,

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1 you should conduct due diligence prior to
 2 shipping that order --
 3 Q. And if --
 4 A. -- or it's a failure of
 5 maintenance of effective controls.
 6 Q. And is there a comment that if
 7 you don't conduct adequate due diligence,
 8 that every order after that flags?
 9 A. No. But that's not typically
 10 anything that would ever be part of a
 11 distributor briefing. That's just outside
 12 of, you know, any kind of discussion related
 13 to that matter.
 14 Q. Has that been part of any
 15 discussion that you know of that DEA has had
 16 with any distributor?
 17 MR. FULLER: Objection.
 18 If you know.
 19 MR. BUSH: If you know. Sure.
 20 Of course it's if you know.
 21 A. I think it's touched on in the
 22 letters by Mr. Rannazzisi. I think it says
 23 if you continue to distribute controlled
 24 substance prescriptions and you don't dispel
 25 those prescriptions, I think it could lead up

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1 to revocation of your DEA registration.
 2 So I think there's comments
 3 that would apply to that same topic or issue
 4 minimally in his letters.
 5 I know they're discussed in
 6 distributor briefings. I'm also aware of
 7 some industry presentations where it makes
 8 that same statement. It was a pretty
 9 consistent statement that the DEA was putting
 10 out, for sure after 2005 -- or 2006 letters.
 11 BY MR. BUSH:
 12 Q. I want to be really specific
 13 about this because I think you've mushed
 14 together a whole lot of concepts here. I'm
 15 focused very specifically on if you do
 16 inadequate due diligence, everything else
 17 after that is a suspicious order. That's an
 18 assumption of your application of these
 19 methodologies. Was that --
 20 A. Did you say inadequate? I'm
 21 sorry.
 22 Q. Yes, I said inadequate.
 23 A. Yes, that's my assumption.
 24 Q. And is there anyplace where
 25 DEA, including the Rannazzisi letters, says

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1 that's what happens? That's not the same as
 2 what you said that you have an inadequate
 3 system of -- to control for diversion or --
 4 I'm not talking about that.
 5 I'm just saying: The concept
 6 that everything after an inadequate due
 7 diligence is flagged as a suspicious order,
 8 is that ever said anywhere by DEA to
 9 distributors?
 10 A. I want to review something in
 11 my report. Just a second, please.
 12 Q. Sure.
 13 MR. FULLER: If you want to
 14 pull the Rannazzisi letters like he
 15 suggested, you can.
 16 MR. BUSH: I didn't actually
 17 suggest that.
 18 MR. FULLER: You said in the
 19 Rannazzisi letters. He'd have to look
 20 at them.
 21 MR. BUSH: I said including.
 22 He's mentioned them already.
 23 (Document review.)
 24 A. So the Rannazzisi letter, the
 25 first one in 2006, he doesn't specifically

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1 state the same thing as you have stated.
 2 BY MR. BUSH:
 3 Q. Right.
 4 A. But he does make the statement
 5 that in addition to reporting all suspicious
 6 orders, a distributor has a statutory
 7 responsibility to exercise due diligence to
 8 avoid filling suspicious orders that may be
 9 diverted into other than legitimate medical,
 10 scientific and industrial channels. Failure
 11 to exercise due diligence could, as
 12 circumstances warrant, provide a statutory
 13 basis for revocation or suspensions of a
 14 distributor's registration.
 15 Q. Right.
 16 A. And although it's not exactly
 17 the same statement, I think it addresses the
 18 same concept as we're discussing.
 19 Q. It's not even close to the same
 20 statement, is it, Mister --
 21 A. Well, I think it is.
 22 MR. FULLER: Form.
 23 BY MR. BUSH:
 24 Q. It doesn't say anything about
 25 what flags, if you don't do adequate due

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1 diligence on an order. That -- what you just
2 read says nothing about that, right?
3 A. It does not say --
4 Q. Okay.
5 A. -- that it would flag all
6 subsequent orders, but it does say if you
7 don't do the due diligence, you could lose
8 your DEA registration.
9 Q. Have you done any calculation
10 of what the impact is of the assumption that
11 everything flags after one failure to do due
12 diligence?
13 A. I have not. You mean in terms
14 of denial of controlled substances to the two
15 counties? Is that --
16 Q. Well, in terms of the number of
17 orders that are -- or the percentage of
18 orders that are flagged for each one of the
19 distributor defendants in this case.
20 A. In regards to?
21 Q. Well, say -- take a look at
22 page 41.
23 A. Okay.
24 Q. This is by dosage units, I
25 understand.

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1 A. Yes.
2 Q. But if you look at the CVS line
3 for Cuyahoga County on page 41, you've got
4 95.7% of the total dosage units are flagged
5 using the trailing six-month threshold?
6 A. I do.
7 Q. And you have 94% of the total
8 dosage units in Summit County that are
9 flagging, right?
10 A. I do.
11 Q. And if you remove the
12 assumption that everything after one failed
13 due diligence effort flags, do you know what
14 those numbers go down to?
15 A. I do not.
16 Q. You have no clue?
17 A. I have no clue.
18 Q. If I told you that in Summit
19 County they go down to 4.3% rather than 94%,
20 and they go down to 4.6% rather than 95% in
21 Cuyahoga, would that surprise you?
22 A. I wouldn't have a comment on
23 those figures.
24 Q. Now, you also have testified
25 already a little bit about whether or not you

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1 reviewed any particular orders, and I think
2 your answer in substance is no, you didn't
3 review any particular orders that might or
4 might not have been suspicious.
5 Is that generally true?
6 A. That's generally true, that's
7 my recollection is I answered that way
8 previously, too, yes, sir.
9 Q. And with respect to any of the
10 orders that are flagged by these
11 methodologies under your and Mr. McCann's
12 analysis, you don't know what happened to any
13 of the drugs that were actually shipped and
14 delivered to CVS Pharmacies?
15 A. I don't have any direct
16 knowledge of what happened to any of the
17 drugs that were distributed to each of the
18 pharmacies. I didn't conduct any analysis as
19 of today that would give me that knowledge.
20 Q. And you don't know whether -- I
21 understand that your opinion is that the due
22 diligence was insufficient by CVS, and we'll
23 get to that in a minute.
24 But you don't know whether any
25 of these orders would have cleared a due

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1 diligence investigation that does meet your
2 exacting standards, do you?
3 A. Could you say that one more
4 time, I'm sorry?
5 Q. I'm just saying you don't know
6 whether any of the orders that are flagged
7 using your and Mr. McCann's methodologies for
8 CVS would have been cleared using what you
9 would say is an adequate due diligence
10 process. You haven't done that analysis.
11 A. So I think what you're asking,
12 is it a hypothetical question?
13 Q. Yes.
14 A. Okay.
15 Q. Well, no, actually it's not.
16 You don't know. I'm asking you. You don't
17 know?
18 A. Well, I guess you're asking me
19 to assume that if CVS had an adequate due
20 diligence system in place and they conducted
21 it? Is that the question? Maybe I don't
22 understand the question.
23 Q. Let's -- if you took your
24 standards for a due diligence system --
25 A. Okay.

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1 Q. -- and you personally, as part
2 of your expert assignment -- I know you
3 weren't asked to do it -- went and looked at
4 each one of the orders that flagged, you
5 don't know today whether it would have passed
6 your own due diligence standards?
7 A. I didn't review any records
8 that I -- on a consistent application by CVS
9 that would have caused that to occur.
10 Q. That's a different question.
11 I'm asking if you take your
12 standards and you apply it -- and you went in
13 and you went back in time and you started to
14 look at all these orders, you don't have any
15 idea whether any of these orders would have
16 passed your exacting standards and you would
17 have determined that they weren't suspicious?
18 MR. FULLER: Object to the
19 question. It is a hypothetical.
20 A. Yeah, I'm not sure I can answer
21 that.
22 BY MR. BUSH:
23 Q. Well, isn't the answer no, you
24 don't know?
25 A. No, it's not no. It's just so

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1 hypothetical, I'm just not going to answer on
2 a hypothetical whether if I went back in time
3 and applied any standards of due diligence to
4 the orders, whether or not they would be
5 cleared.
6 I -- I don't know all of the
7 criteria necessary to make that decision. I
8 just -- it's a hypothetical question. I'm
9 not going to answer it.
10 Q. Haven't you just spent your
11 report and a bunch of your testimony telling
12 us what the criteria are? What do you mean
13 you don't know what the criteria are?
14 A. No, the criteria -- the
15 information -- the distribution information,
16 looking at the due diligence -- or the due
17 diligence files that establish the customer.
18 I mean, there's a whole lot of information
19 other than to just look at an order and apply
20 a due diligence and make a decision on it.
21 It's a more complex analysis than that.
22 So hypothetically, in a
23 hypothetical world, if I went back and I did
24 all of those things, I guess there's always
25 the possibility there could be a different

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1 conclusion, but that's hypothetical, and it
2 didn't occur in this situation.
3 Q. You didn't do it. You didn't
4 go try to do it?
5 A. No, I couldn't do it.
6 MR. FULLER: Hey, Mr. Court
7 Reporter, I think all of our little --
8 aren't working.
9 MS. SWIFT: Mine is working.
10 MR. BUSH: This one is working.
11 (Comments off the stenographic
12 record.)
13 THE VIDEOGRAPHER: Going off
14 the record, 11:21 a.m.
15 (Recess taken, 11:21 a.m. to
16 11:23 a.m.)
17 THE VIDEOGRAPHER: We're back
18 on the record at 11:23 a.m.
19 BY MR. BUSH:
20 Q. Mr. Rafalski, let me ask you to
21 turn to page 96 of your report.
22 MR. FULLER: I'm sorry,
23 Counsel, what page?
24 MR. BUSH: 96.
25 MR. FULLER: Thank you.

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1 BY MR. BUSH:
2 Q. You got -- are you there?
3 A. Yes, sir, I am.
4 Q. You see the sentence that says:
5 Although denied by Vernazza, it appears that
6 the August 25th, 2010 SOM section in the
7 standard operating procedures was rushed into
8 place to comply with a DEA request.
9 Do you see that?
10 A. Yes, sir.
11 Q. Who is Mr. Vernazza?
12 A. You know, I reviewed that.
13 It -- CVS employee. I don't remember his
14 exact title.
15 Q. Were you present at his
16 deposition?
17 A. I was not.
18 Q. What was his testimony?
19 A. I don't recall.
20 Q. Did you --
21 (Telephone interruption.)
22 BY MR. BUSH:
23 Q. Did you review the testimony of
24 Mr. Mortelliti on the subject of the document
25 that you're referring to here, the

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1 August 25th, 2010 SOM section of the standard
2 operating procedures?
3 A. His testimony? I'm sorry.
4 Q. Yeah. Did you review his
5 testimony?
6 A. I don't -- I don't recall that.
7 I don't think I cited it.
8 Q. Did you review the testimony of
9 Mr. Devlin on that subject?
10 A. I don't believe so.
11 Q. So you're contradicting or
12 expressing an opinion on the veracity of
13 Mr. Vernazza's testimony and you haven't
14 actually read the testimony of people about
15 the same subject and you don't recall who he
16 is?
17 A. I recall the name. Exactly who
18 he is, I don't recall.
19 Q. Okay.
20 A. And my opinion is also based on
21 the document, but your correct statement on
22 the -- I don't cite the deposition testimony,
23 and I don't have an independent recollection
24 I reviewed it.
25 Q. Let me ask you -- let me find

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1 this here. Give me a sec.
2 So take a look at the top of
3 page 97, where you refer to the testimony of
4 Amy Propatier. You see where I'm reading?
5 You see where it's referred to, the very top
6 of page 97?
7 A. Yes.
8 Q. It says: The testimony of Amy
9 Propatier who admitted that she was listed as
10 the CVS DEA compliance coordinator in the
11 Controlled Drug - DEA Standard Operating
12 Procedures Manuals, but that title was only
13 for reference in the standard operating
14 procedures and was not her real job position.
15 Do you see that?
16 A. Yes.
17 Q. Why was -- first of all, why is
18 that important to you?
19 A. Well, I think it's indicative
20 of the overall compliance program in place,
21 if she's just in an important position just
22 in title and she's not functioning in that
23 position.
24 Q. Did you read any of the
25 testimony about what she was actually doing

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1 in that position?
2 A. I reviewed the deposition. I
3 don't have any independent recollection of
4 all of the -- of what you just said, but I
5 did review it.
6 Q. And do you know what the
7 definition of a coordinator is?
8 A. Generally speaking, yes.
9 Q. Give me your definition.
10 A. Someone that would oversee
11 or -- I don't want to use the same word,
12 coordinate, but it would oversee and direct
13 individuals or operations.
14 Q. Did you read the testimony of
15 Ms. Propatier who said that her job was to be
16 a central point of contact and keep a
17 consolidated point of contact for all our
18 DCs, meaning distribution centers, to get
19 information to support them? Did you read
20 that testimony? It's not referred to in your
21 report.
22 A. I know it's not referred to.
23 I'm trying to have -- I don't have an
24 independent recollection that I did.
25 Q. And did you read the testimony

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1 of any of the people -- let's say Dean
2 Vanelli who worked with her about what he
3 thought she was doing?
4 A. If I didn't cite it, I'm not
5 sure that I reviewed it.
6 Q. Okay. And that would be true
7 of any of the other CVS employees who
8 testified about what they thought Amy
9 Propatier's job was?
10 A. I did not review every
11 deposition from CVS.
12 Q. Do you remember any other
13 deposition that you reviewed from a CVS
14 person on the subject of Amy Propatier's job
15 functions?
16 A. I do not have any independent
17 recollection of that.
18 Q. Do you think that it is
19 inevitable that every distributor will have
20 some suspicious orders that should be
21 reported to DEA?
22 A. No, I don't think it's
23 inevitable.
24 Q. Okay.
25 A. I draw that conclusion from my

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1 experience, and again, it's -- I think it's
 2 highly dependent on the vetting of customers
 3 before you come on, the scope of your
 4 business and the type of your business.
 5 So I could easily see some
 6 business scenarios where it would be a low,
 7 very low possibility a suspicious order would
 8 occur.
 9 Q. So let me ask you to take a
 10 look at your page -- I think it's 104. Let's
 11 go there together. Maybe it's not. Hold on.
 12 I'm just going to move on with this, except,
 13 I think you may remember it yourself, but at
 14 some point you say that the increase in the
 15 prescription opioids without any due
 16 diligence documentary basis is indicative of
 17 a failure to maintain effective control
 18 against diversion.
 19 Is that --
 20 A. Read that one more time, I'm
 21 sorry.
 22 Q. Yeah. The increase in
 23 prescription opioids without any due
 24 diligence documentary basis is indicative of
 25 a failure to maintain effective control

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1 against diversion.
 2 That was -- I'm sorry, it's not
 3 where I thought it was in here, which is why
 4 I'm not showing it to you.
 5 A. I don't think I would make that
 6 statement, but if it's in my report, if you
 7 could point it out to me.
 8 Q. Yeah. Well, here's -- I'm not
 9 going to do that just because of the
 10 shortness of time, but what I do want to talk
 11 about is documentary basis, which you've
 12 talked about with some other people.
 13 But did you read the testimony
 14 of John Mortelliti about his explanation for
 15 the absence of his due diligence records?
 16 A. Yes, I believe, but can I --
 17 Q. Let me refresh your
 18 recollection if --
 19 A. Well, let me look -- go ahead.
 20 Q. Do you recall that he testified
 21 that he kept notes on the IRRs for each IRR
 22 that he reviewed, and that he kept them in
 23 his office, and then when people asked for
 24 them in this case, he went to try and find
 25 them, and people at his facility said that

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1 they had thrown them out because they were
 2 way more than three years old?
 3 A. I have a recollection of that
 4 general testimony --
 5 Q. Okay.
 6 A. -- that they couldn't be
 7 produced, but he said that that -- not
 8 agreeing exactly that's what he said, but he
 9 did say that he reviewed them, initialled
 10 them and then sent them out, and none of them
 11 could be disclosed. I do have a recollection
 12 of that.
 13 Q. Okay. So the inability to
 14 disclose the due diligence records, at least
 15 during the time that he was there, is because
 16 they were being asked for, let's see, some
 17 times in 2018, which is nine or ten years
 18 after he was actually creating them?
 19 A. Okay.
 20 Q. Okay. And that's the basis for
 21 your conclusion that he actually didn't
 22 conduct adequate due diligence?
 23 A. That's one of the actions. I
 24 think it was the -- my opinion is also based
 25 on the fact that -- I don't think there's any

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1 kind of documentation that would indicate
 2 that occurred independent of what he said.
 3 Q. So let's talk a little bit
 4 about the .15 to .65, the subject that you've
 5 already mentioned once.
 6 A. Okay. Yes.
 7 Q. In that context, didn't
 8 Mr. Mortelliti testify that he consulted with
 9 field loss prevention people who were being
 10 asked to review orders that he was sending
 11 out for further investigation?
 12 A. I believe there was a -- some
 13 limited communication.
 14 Q. How do you know it was limited?
 15 What's the basis for that conclusion?
 16 A. All that I could find was
 17 limited. It wasn't extensive. I believe I
 18 have a recollection that there was a
 19 communication or there was some
 20 communication, but not to the level of the
 21 number of IRRs that were distributed out to
 22 the field.
 23 Q. But the fact that
 24 Mr. Mortelliti was consulting with them in
 25 connection with trying to calibrate the score

<p style="text-align: right;">Page 596</p> <p>1 suggests, does it not, that there was active 2 communication because they didn't want to 3 have to review orders that were false 4 positives? 5 A. I don't remember the 6 conversation exactly on that context. 7 Q. Okay. I'm going to ask you 8 about another subject here. 9 You remember that you've 10 expressed an opinion about outside vendor 11 orders in the CVS SOM system? 12 A. I did. Any particular page 13 that -- 14 Q. Yeah. I'm going to ask you to 15 take a look at page 106, assuming my 16 references here are better than they were 17 before. 18 So if you take a look at the 19 second full paragraph, you say that the IRRs 20 had some specific problems that fit within 21 the time periods below, but it also had one 22 overarching issue that continued from 23 mid-2009 to March 2014 - when performing the 24 calculation of whether the order was 25 suspicious, the IRRs did not consider orders</p>	<p style="text-align: right;">Page 598</p> <p>1 the main concern in regards to my opinion. 2 It's the fact that they would be distributed 3 to CVS pharmacies and the accountability or 4 the suspicious order system doesn't account 5 for them. 6 And CVS is aware that their 7 pharmacies are receiving those additional 8 same controlled substances, and my opinion 9 says that they have a responsibility to 10 account for those controlled substances. 11 Q. And my question is whether you 12 know what the order of magnitude was of the 13 shipments that came from Cardinal and whether 14 it made a difference. 15 A. Well, that's, I think, a double 16 question. 17 Q. It is. 18 MR. FULLER: Object to form 19 then. 20 A. The first answer I would say 21 is -- I don't know the answer to the first 22 part of your question, but the second part of 23 your question, if it was one bottle, it would 24 be of concern to me. Because it just 25 fails -- so -- if they could receive one</p>
<p style="text-align: right;">Page 597</p> <p>1 delivered to CVS pharmacies by outside 2 vendors. 3 A. That's correct. 4 Q. Okay. And an outside vendor in 5 this context is some distributor other than 6 CVS? 7 A. That's correct. 8 Q. And do you know who that 9 distributor was in the Track 1 jurisdictions? 10 A. I believe I -- it's in my 11 report somewhere. 12 Q. Well, let me suggest to you 13 that it's Cardinal. 14 A. I believe it is, but I didn't 15 want to guess. 16 Q. All right. And do you have any 17 information whatsoever about what the amount 18 of the orders was that was received by CVS 19 pharmacies in the Track 1 jurisdictions from 20 Cardinal? 21 A. Well, the amounts wouldn't be 22 of any concern -- well, I shouldn't say of 23 any concern. 24 The amounts or the total 25 amounts distributed to each pharmacy isn't</p>	<p style="text-align: right;">Page 599</p> <p>1 bottle, they could receive a thousand 2 bottles, and if you don't monitor that or 3 incorporate that in your suspicious order 4 system, the amount of what they receive 5 doesn't matter to me. It's just that they 6 receive them and they're unaccounted for. 7 BY MR. BUSH: 8 Q. But if you receive -- you don't 9 know whether they ever received a thousand 10 bottles from Cardinal? 11 A. No, that was just a 12 hypothetical or just to show the differences, 13 the amount doesn't matter. It's the fact 14 that they weren't monitoring that. 15 Q. And if the amounts were trivial 16 or were consistent over time, it wouldn't 17 have made any difference in the SOM system, 18 would it? 19 A. I think it does make a 20 difference because you don't account for it. 21 And the possibility that it could be a 22 thousand exists and you wouldn't account for 23 it. So I don't agree with that statement. 24 Q. But if the possibility that it 25 could be a thousand never occurred, then it</p>

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1 wouldn't have mattered in your hypothetical.
2 Would you agree with me on
3 that?
4 It's a risk of -- maybe we can
5 grant you that, but if the risk never came
6 home to roost, then it doesn't matter, but
7 you don't know that.
8 A. Well, that's it. The concept
9 of why we're not agreeing on this is the
10 suspicious order system and the effectiveness
11 of it and the due diligence is all based on
12 the risk of diversion. It doesn't mean that
13 diversion is going to occur. Just based on
14 the serious risk, and that's what makes it a
15 maintenance of effective controls requirement
16 by the law.
17 Q. All right. Take a look at
18 page 108. So this -- I want to direct your
19 attention to the top of page 108. You say:
20 Mortelliti testified that while he was
21 reviewing the IRR, every HCP order that
22 appeared on the IRR was referred out for
23 additional investigation which he believed
24 was necessary.
25 With me so far?

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1 A. I do. That was part of his
2 deposition, yes, sir.
3 Q. And then down a couple of
4 sentences later, it begins: Significant
5 evidence exists that calls into question the
6 accuracy of Mortelliti's statement.
7 Do you see that?
8 A. Yes, sir.
9 Q. So, first of all, you are, as
10 an expert here, expressing an opinion on what
11 the evidence shows in the case.
12 Do you agree with me?
13 A. I just think it says the
14 evidence exists that calls into question. I
15 think it questions the evidence because
16 there's conflicting statements.
17 Q. So you're evaluating the
18 evidence?
19 A. I'm not evaluating the
20 evidence. I'm evaluating the veracity of
21 Mr. Mortelliti's statement --
22 Q. Mortelliti.
23 A. Okay. Mortelliti.
24 Q. You're evaluating the veracity
25 of his statement?

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1 A. Based on the conflicts with his
2 testimony compared to other witnesses.
3 Q. And one of the items you cite
4 is that he testified he'd contact the loss
5 prevention manager and pharmacy manager of
6 the distribution center and freeze all orders
7 for HCP that flagged.
8 Do you see that?
9 A. Yes, sir.
10 Q. And you then say that one of
11 the loss prevention managers at the
12 Indianapolis distribution center told the DEA
13 that he had never received a call from John
14 Mortelliti, right?
15 A. That's correct.
16 Q. But we don't know whether or
17 not John Mortelliti called the pharmacy
18 manager or someone else, do we?
19 A. We don't.
20 Q. You don't know that.
21 And you don't know whether or
22 not the orders were, in fact, frozen until
23 they were evaluated, do you?
24 A. I don't know that.
25 Q. You also, second, say that

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1 there are no documents that support this, and
2 further, that I have been informed that the
3 only documents that indicate any
4 investigation was ever done by VIPER analysts
5 are the IRR.
6 You see that?
7 A. Yes, sir.
8 Q. Who informed you?
9 A. Well, the documents informed
10 me, but I think that's one of the areas where
11 I was provided the information and I reviewed
12 it and confirmed it.
13 Q. Do you remember what the
14 information was that you were provided that
15 led you to that conclusion?
16 (Telephone interruption.)
17 A. I believe I was verbally
18 informed, and then I believe, if my
19 recollection is correct, I reviewed some IRR
20 recaps, and there's only a small number of
21 IRR recaps. I believe that's the basis for
22 that statement.
23 Q. And you don't cite anything in
24 a footnote to support that particular
25 sentence that I just --

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1 A. There is no cite here, no, sir.
2 Q. Okay. Now, you mentioned the
3 IRR recaps. Do you remember the time period
4 that the IRR recaps existed that you're
5 referring to?
6 A. I do not, but I could review my
7 report. It may indicate to you.
8 Q. Well, let me suggest to you
9 it's in the first three months of 2011.
10 Did you review any of the
11 testimony to determine whether Mr. Mortelliti
12 was, in fact, reviewing IRRs in the first
13 three months of 2011?
14 A. I believe there was testimony
15 that that is a true statement.
16 Q. Do you remember what it was?
17 A. That he was reviewing the IRRs.
18 Q. Whose testimony?
19 A. I believe it might have been
20 his, but just from recollection of reviewing
21 his deposition.
22 Q. Did you review -- I'm sorry.
23 Did you review anybody else's
24 testimony on the subject?
25 A. I don't believe so, no, sir.

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1 Q. Did you review any of the
2 documents that showed that there were some
3 analysts who were hired at the beginning of
4 the year who were reviewing -- beginning of
5 2011 who were reviewing IRRs?
6 A. At this time, I don't have a
7 direct recollection of that.
8 Q. Okay. So let's take a look at
9 the -- on the same page, 108, Algorithm Not
10 Functioning Correctly - Loses Historical
11 Data - Active Ingredient, that subject?
12 A. Yes.
13 Q. Now, that's part of your
14 opinion that the CVS SOM system was -- I
15 don't want to put words in your mouth, but
16 inadequate?
17 A. Yes. So I actually looked at a
18 considerable volume of those IRRs and
19 observed that the data for the last three to
20 four months was wiped off and it was only
21 zeros, which would affect the calculation or
22 the scoring that would be done. I started to
23 actually do a list of them, but they're so
24 extensive, I didn't conclude.
25 Q. And you understand from --

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1 well, did you understand from what you
2 reviewed that CVS was addressing that issue?
3 A. Well, I believe Mr. Mortelliti
4 said that he was going back and researching
5 records and entering the data, but the
6 question I would have is why they still were
7 all zeros in the records that I reviewed, if
8 that answers your question.
9 Q. No, that doesn't exactly answer
10 my question.
11 Do you understand that steps
12 were being taken to include or to report
13 shipments on the IRR by active ingredient to
14 change the Buzzeo system so that it worked by
15 active ingredient?
16 A. I don't have a direct
17 recollection of that.
18 Q. Okay. Now, you did refer to
19 what Mr. Mortelliti said he was able to do,
20 but it don't sound like you have the clearest
21 recollection of what he said he was able to
22 do.
23 You want to try and --
24 A. Well, I think he was going back
25 and re -- he was reentering the data or --

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1 that's my recollection. There was some -- he
2 was taking some action to try to correct the
3 missing data.
4 Q. Okay. Do you recall that he
5 went back and reviewed all the IRR reports
6 that he had that had the data on them so that
7 he could fill in the blanks?
8 A. I do, and that's what I thought
9 I said, but then when I looked at all of
10 these forms and they all had zeros, the
11 blanks weren't filled in, so I'm not sure why
12 the zeros would appear. But I didn't have a
13 chance to ask Mr. Mortelliti why that would
14 be.
15 Q. Well, I don't think he said
16 that they were filled in, but even if they
17 were, it would be on the records that he
18 kept, which no longer exist.
19 A. Well, I can't speak to that.
20 But all I --
21 Q. All right.
22 A. All my opinion was based on was
23 that it was -- that there were decisions
24 being made on those specific IRRs and the
25 algorithm was -- had zeros in there. So I

<p style="text-align: right;">Page 608</p> <p>1 couldn't draw a conclusion that there would 2 be a recalculation if the proper data was 3 entered in them. 4 Q. What was the effect of the loss 5 of order history? More flags or fewer flags? 6 A. I believe that -- and it's a 7 very complex -- before I make a comment on 8 that, it's a pretty complex algorithm, and it 9 takes into effect some binary calculations 10 and different ratios and odds. But I would 11 say if the zeros appeared, it would probably 12 increase the score of the system, just based 13 on my attempted analysis of it. 14 Q. And do you recall that that's 15 what Mr. Mortelliti testified, that it 16 actually increased the number of flags that 17 he had to review and the loss prevention 18 people had to review? 19 A. Yes, but I went in and tried to 20 see if that was actually accurate, and I 21 believe by looking at the algorithm, that is 22 probably an accurate statement. 23 Q. An accurate or inaccurate? 24 A. An accurate. 25 Q. Okay.</p>	<p style="text-align: right;">Page 610</p> <p>1 MR. BUSH: 26, yeah. 2 MR. FULLER: Thank you. 3 BY MR. BUSH: 4 Q. Is this at least part of an IRR 5 that's similar to ones that you reviewed? 6 A. Yes, sir. 7 Q. Can you take a look at the last 8 page of the document? 9 A. Yes, sir. 10 Q. Okay. Can you tell me -- let's 11 walk through this. 12 A. Which particular order? 13 Q. Let's pick the first one, 14 store, what's that? 15 A. That's the store number, 3306. 16 Q. And what is that? 17 A. That's the store number of the 18 CVS store, store number 3306. 19 Q. That's doing what? 20 A. It's telling CVS which physical 21 location it is. 22 Q. This is the store that's 23 ordered the drugs, right? 24 A. Well, yes. I thought you meant 25 like --</p>
<p style="text-align: right;">Page 609</p> <p>1 A. I could explain to you why I 2 drew that conclusion, or... 3 Q. No. 4 A. Okay. 5 Q. That's fine. What are we up to 6 here, 26? 7 (Whereupon, Deposition Exhibit 8 Rafalski-26, Consumer Value Stores IRR 9 Report, CVS-MDLT1-000100763 - 10 CVS-MDLT1-000100768, was marked for 11 identification.) 12 BY MR. BUSH: 13 Q. Let me show you what's been 14 marked as Exhibit 26. 15 MR. BUSH: My apologies, I gave 16 you -- actually, give that to him. I 17 need this. 18 MR. FULLER: Indian giver. 19 BY MR. BUSH: 20 Q. I gave you one that has a 21 highlight or two on it, but I put that on 22 there. 23 A. Okay. 24 MR. FULLER: I'm sorry, what 25 number is this, 26?</p>	<p style="text-align: right;">Page 611</p> <p>1 Q. What's the next number? 2 A. I don't know. 3 MR. FULLER: Form. 4 BY MR. BUSH: 5 Q. What's the SOM key? 6 A. So there's a combination of 7 numbers here, just so I can make a 8 clarification. So there's a number, a 9 six-digit number that's -- I don't know what 10 that would be. It's possible it's an order 11 number. But the last number is a 7, and the 12 7.5/200-milligram, that's the strength of the 13 drug. 14 Q. Okay. 15 A. It's kind of under the SOM key 16 field. 17 Q. Uh-huh. 18 A. Okay. 19 Q. It's hydrocodone? 20 A. Yes. 21 Q. What's the item number? 22 A. 353756, and my experience would 23 indicate to me that that's an item number 24 that's assigned to it by the CVS corporation. 25 Q. Okay. Let's skip over a little</p>

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1 bit to bill quantity. What's that?
2 A. That's the billing quantity.
3 That's the order that -- or the amount that's
4 billed internally to CVS and the quantity is
5 five, so it would be five bottles.
6 Q. Okay. And the unit of measure
7 is what?
8 A. A hundred dosage units in a
9 bottle.
10 Q. Okay. And the extended
11 quantity is?
12 A. 500.
13 Q. Which is the --
14 A. That's the total number of
15 dosage units. It calculates the five bottles
16 at 100 a bottle.
17 Q. All right. What is -- going
18 down to the next line, what does Drug 1
19 signify?
20 A. Well, we would have to go back
21 to the chart, but I believe that signifies a
22 hydrocodone product, but I'm not exactly
23 sure. I don't think that information is
24 provided here.
25 Q. All right. And what's binary

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1 day?
2 A. If I look back at the sheet
3 prior, it describes binary day, it's an
4 indicator that detects if the GNC is subject
5 to frequent ordering. Possible values,
6 one -- this is a binary calculation. One, if
7 five days or less has passed since the last
8 order. Zero for orders six days or more.
9 And then the interpretation,
10 the frequent ordering of a controlled
11 substance could indicate suspicious behavior.
12 And then the model weight, I believe that
13 that's an assignment that was -- or a value
14 that was assigned in doing a calculation in
15 looking at the probability of diversion.
16 Q. So if I take you through all
17 the rest of the headings on this line, would
18 it be fair to say that you're going to look
19 at the front page and read what it says on it
20 for what that factor is and how it was used?
21 A. I think that's a good
22 assumption. I haven't memorized these, but I
23 have spent some time trying to understand and
24 analyze this system.
25 Q. And you've not reached an

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1 opinion on whether or not this algorithm was
2 an adequate or an inadequate algorithm for
3 purposes of flagging orders that might be
4 suspicious?
5 A. I have an opinion that it's
6 inadequate.
7 Q. And -- okay. What's the basis
8 for that opinion?
9 A. Because according to
10 Mr. Mortelliti, it isn't working.
11 Q. You're talking about because of
12 the loss of order history?
13 A. No, I'm talking about there
14 seems to be a problem because it's generating
15 so many orders. There's not a confirmation
16 that I was able to find if it's generating
17 too many suspicious orders that are
18 suspicious, but it would indicate that this
19 system is generating so many orders that
20 Mortelliti, in his testimony, is asking for
21 help because he doesn't believe it's working
22 effectively.
23 So the issue why that would be
24 bad as far as for a suspicious order system
25 or maintenance of effective controls is when

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1 it's defective and it generates a high volume
2 of orders, there is the potential among those
3 that there are real suspicious orders.
4 Q. So you agree that it was a good
5 thing for CVS to be trying to recalibrate the
6 scoring system so that it was not generating
7 so many false positives?
8 A. So I'm going to say that
9 something definitely needed -- had to be done
10 to fix the system, but I'm not going to agree
11 that just recalibrate it in the manner that
12 occurred was the proper thing to do.
13 Q. All right. Are you a
14 statistician?
15 A. I am not.
16 Q. Do you have any idea how an
17 algorithm works?
18 A. Somewhat. I've -- I used -- I
19 was a math major for a while, so...
20 Q. Can you go in and -- could you
21 have gone in and evaluated the algorithm that
22 was used by Buzzeo and reached an opinion on
23 whether or not it was adequate to flag orders
24 for review?
25 A. Not without a system --

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1 assistance from a computer programmer,
 2 because I think it would take a -- I tried to
 3 do it longhand and I could not, so I think it
 4 would take a computer programmer. But if I
 5 had one with me and I could tell him exactly
 6 what I wanted to do, I think it's possible I
 7 could recreate it.

8 Q. In any event, you haven't done
 9 it?

10 A. I have not. I have not been
 11 able to do it and I tried.

12 Q. And you have no opinion on
 13 whether or not -- well, I guess you said you
 14 do have an opinion.

15 So why do you have an opinion
 16 other than that it was flagging too many
 17 orders? Is there any other basis for your
 18 opinion that the algorithm itself didn't
 19 work?

20 A. Well, when I -- I think it was
 21 confusing to the employees. I think when
 22 they look at an IRR, I don't think they
 23 understood it, and I also think they relied
 24 on just the data on the IRR, and I think this
 25 was only just the trigger for a suspicious

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1 order, and I don't think that they even
 2 understood what the trigger was, what was
 3 causing it, when they -- when this system put
 4 the three different size, frequency and
 5 pattern into one calculation, my recollection
 6 is, is that was confusing to the employees.

7 Q. That seems to me to be talking
 8 about what the employees did with the IRR,
 9 and I'm asking you whether or not the IRR
 10 itself, the algorithm that produces the IRR,
 11 was inadequate for -- in any basis -- for any
 12 basis other than the period when it was
 13 flagging too many orders.

14 A. I think it was inadequate when
 15 the score was raised without taking into
 16 consideration the model weights, and I know
 17 that there was a subsequent change that
 18 eventually Buzzeo did where he added some
 19 attributes and he adjusted the model weights.
 20 So there was some attempt at correction,
 21 so...

22 Q. And you've done no -- made no
 23 effort to calculate how many orders were
 24 flagged before it was recalibrated, how many
 25 orders were flagged after the so-called

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1 retunement where the factors were adjusted?
 2 You've made no calculations along those
 3 lines, have you?

4 A. Well, in forming my opinion, I
 5 saw some communications where
 6 Mr. Mortelliti -- I'm going to say his name
 7 wrong, I'm sorry -- where he was advised by
 8 Buzzeo that if he was to adjust the score, he
 9 should run some analysis and do some
 10 documentation to show that by just raising
 11 the score it didn't change the results or
 12 stop the identification of suspicious orders.
 13 And I failed. I looked and I failed to find
 14 any of that documentation that that actually
 15 occurred.

16 Q. You saw that in the e-mails
 17 where he was actually running -- or asking IT
 18 to run the recalibrations, right?

19 A. I saw that.

20 Q. Right.

21 A. But that doesn't answer the
 22 question on whether or not the system is
 23 effective. So when the system would generate
 24 suspicious orders, it would be the subsequent
 25 due diligence that would indicate, yes, we

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1 have it right because this is a suspicious
 2 order, or it's still generating orders that
 3 aren't suspicious.

4 And the other potential problem
 5 is that with -- because all of this
 6 algorithm, complex algorithm, is based on
 7 model weights that by raising the score, it
 8 doesn't fix the problem because if it's
 9 generating too many suspicious orders,
 10 there's a problem in the design.

11 I think there was one -- I
 12 remember reading either a deposition or a
 13 communication where there was a -- one of the
 14 issues that they believe was the problem was
 15 the first order of a new drug might cause a
 16 trigger, and I think that's one of the things
 17 that Mr. Buzzeo corrected on subsequent
 18 system.

19 MR. BUSH: When did I start?
 20 MR. FULLER: Plenty of time.
 21 (Comments off the stenographic
 22 record.)

23 BY MR. BUSH:

24 Q. I'm going to jump to another
 25 page here, if I can ask you to take a look at

<p style="text-align: right;">Page 620</p> <p>1 PDF 111 -- I'm sorry, 111. 2 MR. FULLER: Are we done with 3 that exhibit? 4 MR. BUSH: Maybe. Maybe. 5 MR. FULLER: Okay. 6 A. I'm on page 111, sir. 7 BY MR. BUSH: 8 Q. Yeah. And I direct your 9 attention to sub -- or paragraph (c), less 10 than 5%? 11 A. Okay. 12 Q. And here you're talking about 13 Gary Millikan and you say that he said he 14 probably reviewed less than 5% of all flagged 15 orders. That's generally the subject matter 16 of that paragraph, right? 17 A. It is, based on his deposition. 18 Q. And by the way, the IRR 19 includes more than just hydrocodone, right? 20 A. Yes, sir. 21 Q. Hydrocodone products? 22 A. Yes, sir. 23 Q. And did you review his 24 testimony? You cite some of his testimony on 25 footnote 476 and 477, but do you recall</p>	<p style="text-align: right;">Page 622</p> <p>1 Rafalski-27, Consumer Value Stores IRR 2 Report, CVS-MDLT1-000100672 - 3 CVS-MDLT1-000100757, was marked for 4 identification.) 5 BY MR. BUSH: 6 Q. So I'm going to show you what's 7 been marked as Exhibit 27, which is an IRR 8 from -- I can't even read the damn thing. 9 MR. FULLER: Wrong glasses. 10 MR. BUSH: Yeah, wrong glasses. 11 BY MR. BUSH: 12 Q. From August 30th, 2013. 13 MR. FULLER: Glad you're not 14 showing it to me then. 15 MR. BUSH: Look over his 16 shoulder. Better than I can do. 17 MR. FULLER: You don't have any 18 other copies, right? 19 MR. BUSH: No, I don't, sorry. 20 A. August 30th, 2013, yes, sir. 21 BY MR. BUSH: 22 Q. Okay. And I'd like to direct 23 your attention to the -- I guess it's the 24 Bates page 10693. It's probably where that 25 blue tab is, I'm just guessing.</p>
<p style="text-align: right;">Page 621</p> <p>1 reviewing his testimony about reviewing 5% of 2 the orders, estimating that he reviewed 5% of 3 the orders? 4 A. Yes, sir. 5 Q. Okay. Do you also recall his 6 testimony looking at specific IRRs about why 7 he could determine from the IRR that no 8 further investigation was necessary? 9 A. I have a recollection of that 10 being in his deposition, but -- 11 Q. Do you recall what he said? 12 A. No, I do not. 13 Q. But you disagreed with him, 14 right? 15 A. Well, I think that was one of 16 the concerns that -- just looking at the data 17 contained in the IRR and being that it was 18 a -- combined with all three, I'm not really 19 sure that it was sufficient to just look at 20 the IRR and make a decision on a suspicious 21 order. 22 Q. Apologies, but I only have one 23 of these, so I'm going to show it to you and 24 ask you some questions about it. 25 (Whereupon, Deposition Exhibit</p>	<p style="text-align: right;">Page 623</p> <p>1 A. It is. Back side. 2 Q. All right. And there is an 3 order on there that Mr. Millikan said he 4 could look at that order and look at the data 5 on the IRR and determine that it did not need 6 any further investigation. He could 7 determine it was not a suspicious order and 8 did not need to be reported to the DEA. 9 And -- let me look over your 10 shoulder here. Right. That's it. 11 Do you have -- 12 (Interruption by the 13 videographer.) 14 MR. FULLER: He was just 15 telling me I'm in the shot, but since 16 we only have one copy. 17 MR. BUSH: That's fine. 18 MR. FULLER: Thanks. 19 BY MR. BUSH: 20 Q. Do you disagree with that? 21 MR. FULLER: Form. If you want 22 to show him the testimony. 23 MR. BUSH: I'm trying to get 24 through. 25 MR. FULLER: I understand.</p>

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1 A. I really don't have sufficient
2 information to make an opinion on that.
3 BY MR. BUSH:
4 Q. All right. Take a look at
5 page 10696, and there's an order there.
6 Mr. Millikan testified similarly that he
7 could look at that and see that there was no
8 need for any further investigation beyond
9 looking at the data on the IRR.
10 Do you disagree with that?
11 MR. FULLER: Same objection.
12 A. Well, the score is below the
13 reporting amount so I don't think it's a
14 suspicious order.
15 BY MR. BUSH:
16 Q. What's the score?
17 A. .06.
18 Q. Okay. Why was it reported on
19 the IRR?
20 A. Could be a problem why the
21 system was flawed.
22 Q. Got it. But you don't disagree
23 with him that he could tell from -- it was on
24 the IRR. He looked at it, said that he could
25 tell that it didn't need to be further

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1 investigated because, from the data on it, it
2 was not a suspicious order?
3 A. Maybe he just looked at the
4 score.
5 Q. Actually, what he said was that
6 it's one bottle. What am I supposed to do,
7 call the pharmacy and say you've ordered one
8 bottle? It's too much?
9 A. No, I agree with that
10 statement. But the score didn't -- shouldn't
11 have even triggered it for a review, so I
12 don't -- I don't know if that was his
13 testimony that you characterized, but...
14 Q. Okay.
15 MS. SWIFT: I'm sorry to
16 interrupt, but I'll just note that the
17 phone has been disconnected again.
18 MR. BUSH: Let's go off the
19 record for a second, and I may be
20 pretty much done so that I don't
21 offend any of my colleagues.
22 THE VIDEOGRAPHER: Going off
23 the record, 12:05 p.m.
24 (Recess taken, 12:05 p.m. to
25 12:07 p.m.)

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1 THE VIDEOGRAPHER: Back on the
2 record at 12:07 p.m.
3 BY MR. BUSH:
4 Q. Just one or maybe two
5 questions.
6 Going back to your testimony
7 when I was asking you about any basis you had
8 for concluding that -- withdrawn.
9 I was asking you about whether
10 any of the methodologies that you have used
11 here, as they were actually used by any
12 registrant, had the feature that once a --
13 once an order was triggered, if there was
14 inadequate due diligence, that everything
15 else after that flagged.
16 And specifically I was asking
17 you whether there was anything that you could
18 point to that DEA had ever said that
19 suggested that was the way it works.
20 And the only thing you pointed
21 me to is one of the Rannazzisi letters. Is
22 there anything else?
23 A. I stopped there. I'm pretty
24 confident if I looked -- if you'd like me to,
25 I could look up the 2007 letter and I believe

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1 it also will make the same statement.
2 Q. Anything else? I'm not going
3 to ask you to do that, but I know what that
4 letter says.
5 A. I believe it was consistently
6 provided to registrants in training. I'm
7 confident without having it in front, I could
8 get it out, the Houston training conference
9 that we had discussed earlier for Mr. Mapes,
10 I believe there was a statement in regards to
11 continuing to ship suspicious orders. So
12 those are a few of the instances.
13 If CVS had a distributor
14 briefing, and I don't have a direct
15 recollection if they did or not, they would
16 have had that same information provided to
17 them.
18 Q. And just to be clear, because I
19 just want to make sure I understand what
20 you're saying, that the information that
21 registrants would have gotten was that if
22 they did not have an effective system, SOM
23 system, in place, they could lose their
24 license?
25 MR. FULLER: Object to form,

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1 misstates prior testimony.
2 BY MR. BUSH:
3 Q. Or was it something else?
4 A. Yes.
5 Q. I'm just asking, what is the
6 something else?
7 A. I think it -- I think -- and I
8 could read this statement again for you out
9 of the 2006.
10 Q. No, you don't need to do that.
11 A. I believe it said if a system
12 identifies a suspicious order and you
13 continue to ship that order without
14 dispelling the potential for diversion, then
15 that act could lead to the removal of your
16 DEA registration.
17 Q. All right.
18 A. So --
19 Q. That's the same -- sorry.
20 A. -- under -- and so that removal
21 would be as a result of maintenance to
22 maintain effective controls to prevent
23 diversion.
24 Then the conclusion would be if
25 you don't dispel diversion, all the

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1 subsequent orders could also be diversion
2 because you have no knowledge because you did
3 no due diligence.
4 Q. But none of the letters or any
5 of the other references that you just gave me
6 actually have that last piece in it, right?
7 A. They don't specifically say
8 that.
9 MR. BUSH: Okay. I am going to
10 conclude. I'm going to make the same
11 statement that others have made that I
12 was not able to get through everything
13 that I would like to have covered with
14 you. You have extensive opinions and
15 have covered a lot of different ground
16 related to CVS's SOM system, but in
17 light of the shortness of time, I'm
18 going to conclude here, but I'm
19 reserving my right to come back and
20 ask further questions.
21 THE WITNESS: It's been a
22 pleasure. Nice to meet you.
23 THE VIDEOGRAPHER: Going off
24 the record at 12:10 p.m.
25 (Recess taken, 12:10 p.m. to

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1 12:52 p.m.)
2 THE VIDEOGRAPHER: We're back
3 on the record at 12:52 p.m.
4 EXAMINATION
5 BY MR. O'CONNOR:
6 Q. Mr. Rafalski, good afternoon.
7 I'm Andrew O'Connor.
8 A. Good afternoon, Mr. O'Connor.
9 Q. I represent Mallinckrodt in
10 this case. I'll be asking you some questions
11 on behalf of manufacturers as well as
12 Mallinckrodt in particular.
13 Mr. Rafalski, would you agree
14 that manufacturers primarily sell to
15 wholesale distributors?
16 A. My experience as a DEA
17 investigator would agree to that statement,
18 but I would add that there's nothing that
19 would restrict a distributor from
20 distributing any of their products to other
21 registrants based on their corresponding --
22 I'm drawing a blank on the name of it --
23 coincidental activities in the CFR, so they
24 could be a distributor.
25 So, yes, that's predominantly

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1 what they distribute, but that doesn't mean
2 exclusively, just...
3 Q. Fair enough.
4 So in that situation that you
5 described was the predominant situation, when
6 a manufacturer is selling to a distributor,
7 the distributor places an order with the
8 manufacturer in those circumstances, right?
9 A. Yes, sir.
10 Q. Okay. And the manufacturer
11 ships product to the distributor?
12 A. That's correct.
13 Q. Now, in your report you
14 describe five suspicious order methodologies,
15 correct?
16 A. I do.
17 Q. But your report does not apply
18 any of those five methodologies to orders
19 submitted by distributors to manufacturers,
20 correct?
21 A. That's correct.
22 Q. And so your report doesn't
23 identify any orders received by a
24 manufacturer that were suspicious, correct?
25 A. I don't think that it says

<p style="text-align: right;">Page 632</p> <p>1 that. It's just that I wasn't tasked to 2 provide that methodology in regards to 3 manufacturers at this time. 4 Q. I understand. But your report 5 doesn't identify any suspicious orders that 6 were submitted by distributors to 7 manufacturers. 8 A. My report would only identify 9 those orders that the manufacturers have 10 identified. I don't make any independent 11 calculations or apply any algorithms to 12 identify it outside of what's in my report 13 stated as I've discovered as part of this 14 discovery. 15 Q. Okay. So other than the 16 reports that the manufacturers themselves 17 reported to DEA, you have not identified any 18 suspicious orders submitted by distributors 19 to manufacturers, correct? 20 A. Can I ask a clarification? Are 21 you talking about an individual order or are 22 you talking about conduct? 23 Q. I'm talking about individual 24 orders. 25 A. I have not done that as we sit</p>	<p style="text-align: right;">Page 634</p> <p>1 (Document review.) 2 A. I don't believe so, no, sir. 3 BY MR. O'CONNOR: 4 Q. Okay. And at trial, do you 5 intend to offer any opinion regarding whether 6 any particular order submitted to a 7 manufacturer was suspicious? 8 A. If I'm requested to do that 9 analysis by counsel, I guess that would be a 10 possibility. I haven't done the analysis as 11 today, so I couldn't offer that opinion. 12 Q. So as you sit here today, you 13 do not have an opinion on whether any 14 particular order that was shipped by a 15 manufacturer was suspicious? 16 A. I think I have an opinion. 17 Q. But you haven't identified any 18 order, correct? 19 A. I have not identified a 20 specific order, but I have an opinion on the 21 conduct. 22 Q. And are you offering any 23 opinion in this litigation that any 24 particular order that was shipped into Summit 25 or Cuyahoga Counties was suspicious?</p>
<p style="text-align: right;">Page 633</p> <p>1 here today, no, sir. 2 Q. Okay. So your report does not 3 identify any shipments by manufacturers to 4 distributors that you claim should have been 5 reported as suspicious? 6 A. My opinion goes to whether or 7 not there were effective -- or suspicious 8 orders, effective suspicious order systems in 9 place and/or the maintenance of effective 10 controls, the due diligence. I do not do any 11 calculations that would identify any specific 12 orders. 13 Q. Okay. So just to be clear, in 14 response to my question, your report does not 15 identify any shipments by manufacturers to 16 distributors that you claim should have been 17 reported as suspicious, correct? 18 A. I think there's some instances 19 in my report, there was -- there may be a 20 description of a relationship or some 21 transactions between a -- let me think a 22 second. 23 Q. Uh-huh. 24 A. Because I have all of the 25 different companies.</p>	<p style="text-align: right;">Page 635</p> <p>1 A. Yes. 2 Q. Okay. And are you offering any 3 opinion in this litigation that any 4 particular order shipped by a manufacturer 5 into Summit or Cuyahoga County was 6 suspicious? 7 A. I'm sorry, shipped by a 8 manufacturer -- 9 Q. Correct. 10 A. -- to a distributor? 11 Q. That's right. To -- to someone 12 in Cuyahoga or Summit County. 13 A. No, sir. 14 Q. Okay. With respect to a 15 manufacturer, what is a suspicious order? 16 A. Well, if a manufacturer has 17 conducted a sufficient due diligence or 18 onboarding process and they've evaluated the 19 scope of their customers' business and the 20 needs, they would establish a pattern, and 21 that pattern would give them an idea of 22 initially the volume of drugs they need to 23 purchase. 24 Now, if it's brand-new 25 customer -- yours is kind of a hypothetical.</p>

<p style="text-align: right;">Page 636</p> <p>1 If it's a brand-new customer, there's not a 2 pattern or a frequency, but they would start 3 out with what they assess as a legitimate 4 volume, and they would monitor that volume, 5 and if a customer exceeded that, that should 6 trigger as an unusual size. 7 But to give you just a general 8 definition, it's kind of a broad topic 9 because it depends on the scope of business 10 of the manufacturer, of the customer, the 11 type of products, the needs, so the -- prior 12 to ever shipping an order, the importance is 13 to understand what the legitimate needs is of 14 a customer. 15 Q. Yesterday you testified that it 16 was important to understand what a usual 17 order was so that you could determine what a 18 suspicious order was. 19 Do you generally recall that 20 testimony? 21 A. I think that's a general 22 description. I think we were discussing the 23 size, so I think before you would know an 24 unusual size, you would need to know the 25 usual size.</p>	<p style="text-align: right;">Page 638</p> <p>1 baseline information to get a gauge on how 2 much product you'd want to send to them. I 3 don't think you would just send them an 4 amount of product and hope they distribute 5 it. I think there should be some kind of a 6 relationship and identification of a 7 legitimate total. 8 BY MR. O'CONNOR: 9 Q. Besides understanding what type 10 of pharmacy -- or what type of customer or 11 the number of customers a distributor had, 12 what other information would you say a 13 manufacturer needs to know in order to 14 establish a baseline? 15 A. A baseline in regards to size? 16 Q. Correct. 17 A. Well, I think there would be 18 some other factors that they should minimally 19 look at. That would be the ability for the 20 company to actually handle the volume of 21 product on a security aspect, they had 22 sufficient cage or vault depending on the 23 schedule of controlled substance they were 24 purchasing. 25 I think they may want to do</p>
<p style="text-align: right;">Page 637</p> <p>1 And I think that's kind of the 2 simpler way of what I just said, is that if 3 you don't really have a comprehension of what 4 is the legitimate needs of your customer, 5 then you couldn't know an unusual order -- 6 unusual size of an order, I'm sorry. 7 Q. What information would you need 8 to determine what a usual order looked like 9 for a manufacturer? 10 MR. FULLER: Form. 11 THE WITNESS: I'm sorry, you 12 said something? 13 MR. FULLER: Object to form. 14 THE WITNESS: Oh. Sorry. 15 A. I think that's dependent on the 16 skill of your compliance employees. I think 17 you go in and evaluate the distributor. I 18 don't think the distributor would purchase a 19 manufacturer's product with an idea on how 20 they were going to sell it and market it, and 21 I think you would evaluate what their scope 22 of business is and the type of customers they 23 were; how many pharmacies they could 24 distribute to. 25 I think you'd have to get some</p>	<p style="text-align: right;">Page 639</p> <p>1 some analysis of the identifications of the 2 pharmacies, if possible, because it's a 3 potential that in the case of Mallinckrodt, 4 they might already have information about the 5 distribution amounts or the purchase amounts 6 for those pharmacies and some trends. 7 Might do some comparison to 8 like customers. Might look into the 9 geographic location of where the product is 10 intended to be distributed. At least for the 11 Mallinckrodt products, to confirm or deny 12 there might be an issue of a distribution by 13 volume to those specific areas. 14 I think the essential thing is 15 what I said initially. I think you need to 16 get an idea of how many customers that that 17 distributor intends to distribute. 18 And I think if we're talking 19 about the onboarding or the initial amounts 20 that they'll be distributing, I think that a 21 registrant should follow those pretty closely 22 because my experience would indicate that 23 sometimes other registrants aren't that 24 truthful, and not just because they want to 25 divert, although that's one of the</p>

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1 indicators.
 2 Sometimes distributors have, in
 3 my experience of doing the pre-regs, that
 4 they have goals or ideas that they possibly
 5 can't meet or are not feasible. In other
 6 words, that they may request a volume of
 7 drugs and anticipate ordering -- or I mean,
 8 hiring a bunch of new people or they want to
 9 order a large volume of drugs and with an
 10 intention of shipping it to a new geographic
 11 area. Those would be all things I would
 12 consider in deciding on the volume to
 13 distribute.
 14 Q. You mentioned pre-reg. Is that
 15 a preregistration inspection by the DEA?
 16 A. Yeah, I'm sorry, that's kind of
 17 a term. Yes, sir, that's going on-site and
 18 prior to issuing the DEA registration, making
 19 sure that you're confident that the
 20 registrant is in compliance with the
 21 regulations and has an understanding before
 22 you issue the DEA registration.
 23 Q. And during one of these
 24 preregistration visits, would you consider
 25 all the factors that you just listed that

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1 manufacturers ought to consider?
 2 A. I don't know that I would -- I
 3 wouldn't do that specific analysis, but I
 4 would -- I would obviously dig into how
 5 they -- the registrant plans to set up their
 6 suspicious order monitoring system.
 7 So what typically -- typically
 8 would happen in this situation, at least with
 9 me and the people that I would have worked
 10 with in my last career, although I won't tell
 11 them how to do a suspicious order system, I
 12 might ask them questions and expect
 13 responses, and those questions sometimes are
 14 teaching moments.
 15 So if I ask them the question
 16 if they're going to monitor the geographic
 17 description of their drugs, I would hope that
 18 they would -- that would trigger them to say,
 19 wow, we might have to think about it, but I
 20 would never tell them of things they had to
 21 do.
 22 Q. So before the distributor even
 23 gets the registration, DEA has inquired about
 24 things like the geographic distribution of
 25 the products, correct?

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1 A. They wouldn't have inquired
 2 about it, and I wouldn't force those opinions
 3 on a distributor. If they had a viable
 4 system, I may ask some questions to trigger
 5 some areas that I think maybe needed to be
 6 cleaned up.
 7 But I wouldn't go in and
 8 already do a geographic -- well, there
 9 wouldn't be one because the registrant's not
 10 registered. They wouldn't have handled
 11 controlled substances. So really, their
 12 distribution trends couldn't be considered
 13 because they don't have product.
 14 Q. But you'd ask about their
 15 intended geographic distributions?
 16 A. That would be one of the
 17 questions. I'd probably be mostly concerned
 18 about just their business model, what they
 19 intend to do with the drugs, how they -- who
 20 they intend to ship them to.
 21 I try to be alert if there were
 22 some areas that were more prone for diversion
 23 as far as at the current time based on my
 24 knowledge. I'll give you one example. There
 25 was a lengthy period of time where

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1 hydrocodone was a big issue in Houston, so if
 2 I was going to approve a registrant that said
 3 I'm going to distribute hydrocodone products
 4 exclusive to Houston, that would kind of be a
 5 trigger to me to maybe do some deeper
 6 analysis about it.
 7 Q. All right. So I do want to get
 8 back to specifically what you claim
 9 manufacturers should be looking at to
 10 determine whether an order is unusual.
 11 You mentioned a few things.
 12 I'm going to name them, and tell me if I've
 13 missed anything, okay?
 14 You mentioned the number of
 15 customers, the ability to handle the volume
 16 ordered, the composition of the customers,
 17 the geographic location, and that's all I
 18 have.
 19 Were there any other factors
 20 that you think manufacturers --
 21 A. I think there were some others.
 22 I should have probably wrote them down.
 23 Q. As you sit here now, can you
 24 think of any others?
 25 A. I could, but could I just get a

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1 clarification? So I believed that our
2 discussion was about setting that initial
3 threshold just for size.
4 Q. Okay.
5 A. And I don't -- I believe we
6 were speaking about a new customer, so just
7 for clarification.
8 Q. Okay. What I'm looking for,
9 though, is a list of all the factors that you
10 claim in your opinion manufacturers should
11 consider when determining whether an order is
12 suspicious.
13 A. Let me ask you a couple of
14 questions if I could.
15 Q. I'd just like an answer to my
16 question, actually.
17 A. Well, then I can't answer it
18 because I don't have enough foundation
19 information about the manufacturer, how long
20 they've been in business. I mean, there's --
21 just to give a hypothetical answer for
22 that --
23 Q. When you say how long they've
24 been in business, do you mean the
25 manufacturer doing the selling --

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1 A. Yes.
2 Q. -- or the distributor doing the
3 buying?
4 A. Whether they're new or they've
5 actually been engaged in the business for a
6 period of time.
7 Q. Okay. What if they've been
8 engaged in the business for decades, what
9 else would you want to know?
10 A. Well, I'd want to know if they
11 had access to -- I think IQVIA information,
12 chargeback information.
13 Q. Okay. And --
14 A. I --
15 Q. When you say IQVIA information,
16 what do you mean by that?
17 A. It's prescription
18 information --
19 Q. Okay.
20 A. -- that they can purchase.
21 Q. Is there any regulation that
22 you're aware of that requires manufacturers
23 to consider IQVIA data or other prescribing
24 data?
25 A. Well, I think the maintenance

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1 of effective controls under -- both in law
2 and the regulation I think could be
3 interpreted that -- now, I'm not going to say
4 under my opinion that it would force a
5 manufacturer to do that, but I think the
6 knowledge that that information exists and is
7 available should be a consideration for a
8 manufacturer.
9 Q. So your opinion is that the
10 effective controls regulation does not
11 require manufacturers to use IQVIA or
12 prescribing information, correct?
13 A. I would say no, and my answer
14 would be based on the fact, in my experience,
15 I couldn't take probably an administrative
16 action just based on that.
17 Q. Okay.
18 A. The only action I could take is
19 if they did have it and they didn't use it,
20 but just not to order it or purchase it, I
21 couldn't force a manufacturer to do that as a
22 diversion investigator.
23 Q. Okay. So in answer to my
24 question, when you say no, you mean no,
25 manufacturers aren't required to use IQVIA

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1 data under the regulation?
2 MR. FULLER: I'm sorry, to use
3 it or purchase it?
4 MR. O'CONNOR: To use it.
5 A. Yes, if they have it, under the
6 regulation, I believe they have to use it.
7 BY MR. O'CONNOR:
8 Q. So just to be clear, your
9 position today is that a manufacturer is not
10 required to purchase IQVIA or prescribing
11 data, but if they have it, they must use it?
12 A. I believe it provides them with
13 relevant transaction information, and if they
14 have it accessible, they should use it in
15 their compliance program.
16 Q. Do you think the regulation
17 requires them to use it if they have it?
18 A. I do.
19 Q. Which regulation is that?
20 A. Maintenance of effective
21 controls to prevent diversion.
22 Q. Does the regulation say
23 anything about prescribing information or
24 IQVIA data?
25 A. It does not.

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1 Q. And the DEA has never issued
2 any guidance to manufacturers informing them
3 that they were to use IQVIA or prescribing
4 data, did it?
5 A. I don't speak for the DEA, but
6 I'm not aware that they've given any
7 guidance.
8 Q. Okay. You mentioned chargeback
9 data a moment ago. What is chargeback data
10 in your understanding?
11 A. A manufacturer completes a
12 transaction to a distributor or a customer,
13 and that customer is at a set price, and if
14 the customer would like to send back the
15 transaction data to the manufacturer, they
16 get a rebate from the original price of that
17 distribution or sale.
18 It's my understanding that
19 chargebacks have up to a 30-day period before
20 they can be submitted back for, and I don't
21 know that they -- it's like a cash basis. I
22 think it might be like a credit basis that
23 goes into their account. But it's a purchase
24 of the transaction information at a fee or a
25 discount for the sale of that drug.

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1 Q. And is it your opinion that
2 manufacturers are required by statute or
3 regulation to use chargeback data in
4 connection with their suspicious order
5 monitoring program?
6 A. I believe by both the CSA,
7 maintenance of effective controls to prevent
8 diversion, and that same regulation in the
9 CFR.
10 Q. And do either the statutory
11 provision or the CFR provision regarding
12 maintenance of effective controls say
13 anything about chargeback data?
14 A. Not specifically, no.
15 Q. And DEA has never issued any
16 guidance to manufacturers to the effect that
17 they were to use chargeback data in
18 connection with their suspicious order
19 monitoring program, has it?
20 A. I believe they have.
21 Q. And what guidance are you
22 referring to?
23 A. I believe they've held
24 manufacturer briefings with manufacturers,
25 and they've informed them that if they have

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1 chargeback information, they should use that.
2 Q. When were those briefings?
3 A. I believe I cite one in my
4 report. It will take me a few minutes,
5 because I don't want to misstate which...
6 Q. Fair to say you don't recall
7 any off the top of your head here today?
8 MR. FULLER: Object to form.
9 Misstates his testimony. He already
10 said he does recall one, it's cited in
11 his report. Just give him a second.
12 BY MR. O'CONNOR:
13 Q. Fair to say you don't recall
14 any details about any manufacturer briefing?
15 A. Well, no, I recall there was
16 one. I just don't know which distributor it
17 was -- I mean, I'm sorry, which manufacturer
18 it was. I'll get it in a second.
19 Q. Okay.
20 (Document review.)
21 BY MR. O'CONNOR:
22 Q. Other than whatever other
23 example you cited in your report, are you
24 aware of any other manufacturer briefing in
25 which manufacturers were informed that they

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1 were supposed to use chargeback data in
2 connection with their suspicious order
3 monitoring program?
4 A. Yeah. On August 23rd of 2011,
5 I was present at one with Mallinckrodt, and
6 there was a discussion about chargeback
7 information there.
8 Q. Okay. And other than meeting
9 with Mallinckrodt in 2011, are you aware of
10 any other instance in which DEA informed any
11 manufacturer that it was to use chargeback
12 data in connection with its suspicious order
13 monitoring program?
14 A. Let me just look one more
15 place.
16 (Document review.)
17 A. The company I referred to is
18 Actavis, and they received a distributor
19 briefing. I have independent recollection
20 that it did occur, but I'm going to say no,
21 because I didn't cite it in my report.
22 BY MR. O'CONNOR:
23 Q. Okay. And do you have any
24 independent recollection of whether that
25 discussion included a statement by DEA that

<p style="text-align: right;">Page 652</p> <p>1 manufacturers were supposed to use chargeback 2 data in connection with their suspicious 3 order monitoring programs? 4 A. I don't recall if it did. 5 Q. So, in fact, before the meeting 6 with Mallinckrodt that you mentioned, DEA had 7 never publicly, certainly, told anyone that 8 using chargeback data was part of the 9 responsibilities of being a DEA registrant, 10 correct? 11 A. My experience and the 12 information that's available to me would 13 indicate that I'm not aware that the DEA had 14 any knowledge that those existed. 15 Q. Before August 2011? 16 A. No. I think prior to that, but 17 related to the Mallinckrodt investigation, 18 prior to that, I don't know that anyone was 19 aware that that -- that chargeback -- that 20 whole chargeback relationship existed in the 21 industry, at least from everything I've 22 learned about that issue. 23 Q. Have you ever heard the term 24 "know your customer's customer"? 25 A. I have.</p>	<p style="text-align: right;">Page 654</p> <p>1 understand what this idea of know your 2 customer's customer meant, it couldn't look 3 in the regulations, could it, because it's 4 not there? 5 MR. FULLER: Form. 6 A. I think it's encompassed in the 7 maintenance of effective controls. 8 BY MR. O'CONNOR: 9 Q. But to be clear, the 10 maintenance of effective controls regulation 11 does not mention anything about knowing your 12 customer's customer, does it? 13 A. It doesn't give any specific 14 guidance, but I think what it does is it puts 15 a manufacturer or any registrant on notice 16 that their continued use of a DEA 17 registration requires them to take steps to 18 prevent diversion, and I believe that getting 19 that information is one of those steps. 20 But so just -- just so it -- 21 but I guess if your question is does it 22 specifically say that term? It does not. 23 Q. And DEA never issued any 24 guidance to manufacturers informing them of 25 their supposed obligation to monitor -- or to</p>
<p style="text-align: right;">Page 653</p> <p>1 Q. What does that term mean? 2 MR. FULLER: Form. 3 A. Well, manufacturers are in a 4 unique position at the top of the 5 distribution chain, that their products pass 6 through distributors down to pharmacies. 7 So there's a couple concepts 8 within that know your customer's customer. 9 There's, of course, if you have the 10 information that you already have the ability 11 to know, things like chargebacks and IQVIA, 12 that's an example of information, know 13 your -- you know, you know your customer's 14 customer. 15 Secondly, a manufacturer would 16 have the responsibility under the maintenance 17 of effective controls to do an analysis of 18 who their customers are, which would be the 19 distributors. 20 So it would be incomplete to go 21 do an analysis on them when they don't have 22 an understanding of where their products 23 would ultimately go. 24 BY MR. O'CONNOR: 25 Q. If a manufacturer wanted to</p>	<p style="text-align: right;">Page 655</p> <p>1 know their customer's customers, correct? 2 MR. FULLER: Form. 3 A. I know I've reviewed where it 4 was presented at some training, but I'm not 5 sure if that was by an industry or a 6 consultant. 7 BY MR. O'CONNOR: 8 Q. DEA -- 9 A. So I'll say no. 10 Q. DEA -- 11 A. I'm not aware of it. At least 12 I'm not aware they've done it. I'm not 13 saying they have not done it. 14 Q. DEA never published guidance in 15 the Federal Register saying anything about 16 knowing your customer's customer, did it? 17 A. They have not done that. 18 Q. Okay. And they never sent a 19 letter to all manufacturers, for example, 20 saying they were to know their customer's 21 customer, did they? 22 A. I'd like to look at the 2007 23 letter. I think it may say all relevant 24 transaction information, and I would consider 25 that relevant transaction information.</p>

<p style="text-align: right;">Page 656</p> <p>1 Q. But it doesn't say know your 2 customer's customer, does it?</p> <p>3 A. It does not specifically say 4 that term, no, sir.</p> <p>5 Q. Okay. In your report, you 6 suggest that: Using relevant data acquired 7 by a manufacturer for compliance purposes is 8 part of maintaining effective controls to 9 prevent diversion. This obligation was 10 acknowledged by Mallinckrodt in its 11 memorandum of agreement Mallinckrodt entered 12 with the United States in 2017.</p> <p>13 Do you recall that opinion?</p> <p>14 MR. FULLER: What page are you 15 on, Counsel?</p> <p>16 MR. O'CONNOR: We're on 146.</p> <p>17 MR. FULLER: Thank you.</p> <p>18 A. So your question was -- and I 19 need to read this again, this obligation was 20 acknowledged by Mallinckrodt in the 21 memorandum of agreement Mallinckrodt entered 22 with the United States in 2017?</p> <p>23 BY MR. O'CONNOR:</p> <p>24 Q. Correct.</p> <p>25 A. Yes, I agree with that</p>	<p style="text-align: right;">Page 658</p> <p>1 would hope they didn't sign a memorandum of 2 agreement and believe that it was not legal.</p> <p>3 Q. A memorandum of agreement is a 4 contract between a company and the DEA, 5 correct?</p> <p>6 MR. FULLER: Object to form.</p> <p>7 A. Yes. It's -- well, it's 8 more -- it's a little more than a contract.</p> <p>9 BY MR. O'CONNOR:</p> <p>10 Q. Okay.</p> <p>11 A. But essentially, two parties 12 sign it with some obligations. So it's an 13 agreement --</p> <p>14 Q. It's an agreement.</p> <p>15 A. Yes.</p> <p>16 Q. It's an agreement between two 17 parties?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. And you would agree that 20 it's possible for a party to agree through a 21 memorandum of agreement to do more than 22 what's required strictly by the law, correct?</p> <p>23 A. But your question was the 24 legality of that agreement or agreeing to 25 something that -- so if they were to agree to</p>
<p style="text-align: right;">Page 657</p> <p>1 statement.</p> <p>2 Q. And is there any basis for your 3 statement besides the language of the 4 memorandum of agreement itself?</p> <p>5 MR. FULLER: Object to form.</p> <p>6 Same objection as earlier -- or same 7 basis as earlier, sorry.</p> <p>8 A. Well, I would hope if they 9 didn't agree with it, they wouldn't sign the 10 memorandum of agreement, but also in 11 consultation with others, that would help 12 formulate my opinion.</p> <p>13 BY MR. O'CONNOR:</p> <p>14 Q. Consultation with which others?</p> <p>15 A. I think there's a Touhy in 16 place, so I'm worried about getting into the 17 issue on the Touhy letter.</p> <p>18 Q. Okay. So when you say that 19 this obligation was acknowledged by 20 Mallinckrodt in the memorandum of agreement, 21 are you suggesting that Mallinckrodt 22 acknowledged in that agreement that there was 23 a legal obligation to monitor chargeback 24 data?</p> <p>25 A. Yes, I would hope they did. I</p>	<p style="text-align: right;">Page 659</p> <p>1 something that wasn't legal, in my 2 interpretation, it would be illegal. It 3 could always require something more, but it's 4 not -- I'm kind of caught up with the fact 5 that you said whether it was legal or not.</p> <p>6 Q. I didn't mean to suggest it was 7 illegal.</p> <p>8 A. Okay. That's kind of what I 9 took so --</p> <p>10 Q. If that's your opinion, that 11 would be helpful to know.</p> <p>12 My question was really whether 13 it's possible for a company in a memorandum 14 of agreement to agree to do more than the law 15 requires them to do.</p> <p>16 A. No, I don't agree with that. I 17 don't think you could make somebody more -- 18 do more than what's their legal requirement. 19 I think what they acknowledge -- excuse me -- 20 is it was part of their responsibility as a 21 registrant, and it acknowledged that. That's 22 my understanding of what they agreed to.</p> <p>23 Q. Well, if a memorandum of 24 agreement didn't obligate the party to do 25 anything more than the law already required</p>

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1 of them, there wouldn't be a need for the
 2 memorandum of agreement, correct?
 3 MR. FULLER: Object to form.
 4 And disagree.
 5 A. No, I don't agree with that.
 6 BY MR. O'CONNOR:
 7 Q. So just to be clear, your
 8 position is that everything that a party
 9 voluntarily agrees to in a memorandum of
 10 agreement is something they're also legally
 11 required to do?
 12 MR. FULLER: Form.
 13 A. Yes. I don't think there's
 14 anything -- I think we're back to the
 15 illegal/legal. I don't think there's
 16 anything there that's not legally required.
 17 I don't -- I wouldn't -- I
 18 don't understand the question then is that
 19 you would write an MOA to somebody that would
 20 not be legally required. If your question is
 21 would it be greater responsibilities or
 22 greater duties, that would be yes, but they
 23 still would be a legal requirement.
 24 BY MR. O'CONNOR:
 25 Q. So the duties, though,

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1 prescribed in the MOA can be greater than the
 2 duties imposed by statute, fair?
 3 A. No, I don't agree with that. I
 4 think under maintenance of effective
 5 controls, that's a broad regulation, and I
 6 think all of these things fit under there.
 7 I think I could -- I could hold
 8 another manufacturer, if I was still a DEA
 9 diversion investigator. I think the
 10 statements entered because it kind of affirms
 11 that that is a -- to me, that they
 12 acknowledge that that is their
 13 responsibility, because I wouldn't expect
 14 them to do it if they didn't think it was.
 15 Q. Just to be clear, are you
 16 saying that every duty that's imposed on any
 17 registrant through a memorandum of agreement
 18 is by definition also required by the law?
 19 MR. FULLER: Form.
 20 A. Yes.
 21 BY MR. O'CONNOR:
 22 Q. Are you aware of any DEA
 23 guidance that's ever been issued that
 24 supports the statement you just made?
 25 A. In regards to the -- whether

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1 the MOAs are all legal requirements? No,
 2 sir.
 3 Q. Okay. In connection with your
 4 opinion, you examined the suspicious order
 5 monitoring programs of seven manufacturers,
 6 correct?
 7 A. Yes, sir.
 8 Q. And each of those programs or
 9 systems was different from one another,
 10 correct?
 11 A. Yes, sir.
 12 Q. And you believe they all fell
 13 short of the regulatory responsibilities
 14 imposed by the CSA and CFR, correct?
 15 A. Yes, sir. Just to add the
 16 caveat that some of them didn't have systems,
 17 but, yes, sir.
 18 Q. Fair to say of the seven you
 19 saw, you weren't satisfied with any of them?
 20 A. That's correct.
 21 Q. Have you ever come across a
 22 manufacturer's suspicious order monitoring
 23 program that you did think satisfied
 24 regulatory requirements?
 25 MR. FULLER: Form.

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1 A. I can think of one.
 2 BY MR. O'CONNOR:
 3 Q. What was that?
 4 A. I'm not sure I can discuss that
 5 with the Touhy letter.
 6 MR. FULLER: Not if it was
 7 based on an investigation that you did
 8 while an agent.
 9 MR. O'CONNOR: Sorry, are you
 10 not answering that question?
 11 THE WITNESS: That's what I
 12 stated, sir.
 13 MR. O'CONNOR: Okay.
 14 THE WITNESS: Because it's not
 15 publicly readily available that
 16 someone would know that.
 17 BY MR. O'CONNOR:
 18 Q. While we're talking about
 19 Touhy, you have said and your counsel has
 20 stated on a number of occasions yesterday and
 21 today that you're not permitted to speak
 22 about any particular investigation you were
 23 involved in while at the DEA; is that fair?
 24 A. That's not publicly or readily
 25 available.

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1 Q. Okay. And with respect to
2 Mallinckrodt in particular, given those
3 restrictions, is it fair to say that all of
4 the opinions you express in your report are
5 based on materials that you reviewed in
6 connection with this litigation?
7 A. Yes, sir.
8 Q. And your opinions are not based
9 on any other information outside of what
10 you've relayed and referred to in your
11 report?
12 A. Well, it's difficult to --
13 since I worked the case for a period of
14 years, obviously, that there may be things I
15 know that aren't part of the discovery, but
16 the opinion I wrote is only based on the
17 information contained in my report.
18 Q. Okay. And do you intend at
19 trial to offer any information or opinions
20 that are based on something other than what
21 you've cited here in this report?
22 MR. FULLER: Object to form,
23 based on the same basis earlier.
24 A. If the Touhy letter is in place
25 and it's restricted by the government, then I

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1 would not offer anything outside of what's
2 contained in my report or currently contained
3 in the discovery material.
4 BY MR. O'CONNOR:
5 Q. In your report, do you express
6 any opinion as to the adequacy of
7 Mallinckrodt's present day suspicious order
8 monitoring program?
9 A. I do not believe I do.
10 Q. Okay. And just so we're clear
11 about the period of time your opinions do
12 relate to, do you have any opinion with
13 respect to Mallinckrodt's suspicious order
14 monitoring program in 2018?
15 A. I do not.
16 Q. 2017?
17 A. I don't think my report
18 references any time period after 2011.
19 Q. Okay. So fair to say in this
20 litigation, you're not providing any opinion
21 with respect to Mallinckrodt's suspicious
22 order monitoring program after 2011?
23 MR. FULLER: Form.
24 A. At the current time based --
25 I'm sorry.

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1 MR. FULLER: Form. I just
2 objected to the form.
3 Go ahead.
4 A. Based on the report as it
5 stands right here without being amended, it
6 doesn't address any time periods that I can
7 find past 2011, so that would be an accurate
8 statement as of today.
9 BY MR. O'CONNOR:
10 Q. Do you plan to amend your
11 report to add opinions related to
12 Mallinckrodt's program after 2011?
13 A. If requested by counsel, I
14 will.
15 Q. Okay. As you sit here today,
16 do you have any opinions with respect to
17 Mallinckrodt's suspicious order monitoring
18 program after 2011?
19 A. No, I do not.
20 Q. Okay. And as you sit here
21 today, do you have any opinions with respect
22 to Mallinckrodt's DEA regulatory compliance
23 outside of suspicious order monitoring after
24 2011?
25 A. It doesn't appear in my report,

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1 so I wouldn't comment on it.
2 Q. Okay. So you have no opinion
3 on that subject?
4 A. No, I think the Touhy would --
5 if I had an opinion or had knowledge and it's
6 not cited here or it's not a public
7 knowledge, I wouldn't make comment on it.
8 Q. Mr. Rafalski, would you agree
9 that it's possible to have a suspicious order
10 monitoring program in place without a formal
11 written policy?
12 A. In a hypothetical sense?
13 Q. Uh-huh.
14 A. Depending on the scope of
15 business, the size of the business and the
16 intended customers, I believe it could be
17 done manual -- manually, but that's
18 hypothetically based on those factors and
19 probably others.
20 Q. Okay. So just because a
21 company doesn't have a formal written policy
22 does not mean it didn't have a suspicious
23 order monitoring program, fair?
24 A. Hypothetically, that could
25 occur, yes, sir.

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1 Q. Okay. And is it fair to say in
 2 your -- in your opinion, Mallinckrodt's
 3 suspicious order monitoring program during
 4 the time period that you examined it involved
 5 an algorithm?
 6 A. Yes, sir.
 7 Q. Okay. And your opinion is that
 8 that algorithm-based program was not
 9 adequate?
 10 A. Yes, sir. And the reason why
 11 is it used a multiplier, so anytime there's a
 12 multiplier applied, if it's an effectively
 13 designed system, you've established a
 14 threshold for a customer that's their
 15 legitimate use, to give that customer two or
 16 three times more than that established
 17 threshold I don't think is an effective
 18 suspicious order system.
 19 Q. Is it your understanding that
 20 Mallinckrodt's suspicious order monitoring
 21 program consisted solely of an algorithm?
 22 A. That's my understanding in
 23 reviewing records. It did not look at size
 24 or pattern.
 25 Q. Okay. So if Mallinckrodt's

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1 suspicious order monitoring program involved
 2 other aspects besides a multiplier-based
 3 algorithm, your opinion might be different --
 4 MR. FULLER: Form.
 5 BY MR. O'CONNOR:
 6 Q. -- correct?
 7 A. It's a hypothetical. I'd
 8 probably have to know what that basis was,
 9 but there has to be something to establish a
 10 threshold minimally or the usual size order
 11 to know something unusual. Unless I don't
 12 understand the question.
 13 Q. But fair to say your opinion is
 14 based on the assumption that Mallinckrodt's
 15 suspicious order monitoring program consisted
 16 solely of a multiplier-based algorithm, true?
 17 MR. FULLER: Form.
 18 A. Any registrant who just had a
 19 suspicious order system based on size only --
 20 size only would be insufficient to me.
 21 BY MR. O'CONNOR:
 22 Q. But just in response to my
 23 question, is your opinion based on the belief
 24 that Mallinckrodt's suspicious order
 25 monitoring program consisted solely of a

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1 multiplier-based algorithm?
 2 A. So I'm going to answer the
 3 question, but I'm going to apply the two- or
 4 three-times algorithm.
 5 Q. Uh-huh. Okay.
 6 A. And my answer to that would be
 7 yes.
 8 Q. So you're not aware of any
 9 other aspects of Mallinckrodt's suspicious
 10 order monitoring program besides the two- or
 11 three-times algorithm?
 12 A. That's correct.
 13 Q. Yesterday you made reference to
 14 a diversion program manager. A diversion
 15 program manager is in a supervisory capacity
 16 within a field office, correct?
 17 A. Typically they're in an upper
 18 management office in a divisional office.
 19 Q. In a divisional office. Okay.
 20 Where do they fall on the
 21 hierarchy relative to a diversion
 22 investigator, for example?
 23 A. If we're looking at a rank in
 24 organization, generally speaking, it's two
 25 times above. So there would be an

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1 intermediary, generally a group supervisor,
 2 in between a diversion investigator and a
 3 diversion program manager.
 4 Q. So you'd have a group
 5 supervisor and then above that group
 6 supervisor, a diversion program manager?
 7 A. Typically, yes. Not always.
 8 Q. Okay.
 9 A. There may be an office where
 10 there isn't a group supervisor, but
 11 typically, yes.
 12 Q. Okay. And are diversion
 13 program managers generally familiar with
 14 registrants' regulatory obligations?
 15 A. In a general sense, they were
 16 originally diversion investigators so I would
 17 hope so. But I always hate to make
 18 assumptions on someone else's knowledge.
 19 Q. Are you familiar with a
 20 gentleman named Scott Collier?
 21 A. I am.
 22 Q. What is your opinion of
 23 Mr. Collier?
 24 A. I've really never reviewed Mr.
 25 Collier's work or worked with him or for him,

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1 so other than to know he's a diversion
 2 program manager in St. Louis, I really don't
 3 formulate an opinion about him.
 4 Q. Do you have any reason to doubt
 5 his competency?
 6 A. No. As I said, I've never been
 7 in a position to make any judgments about
 8 him, either good or bad.
 9 Q. Are you aware that Mr. Collier
 10 described Mallinckrodt's program as the best
 11 suspicious order monitoring program he had
 12 ever seen?
 13 MR. FULLER: Object to form.
 14 A. Well, I think at the time I'd
 15 answer that, now it would go back to that
 16 Touhy issue, so I don't recall seeing any
 17 documents in formulating my opinion to that
 18 effect.
 19 BY MR. O'CONNOR:
 20 Q. Let me ask it this way: Would
 21 it change your opinion to learn that a
 22 diversion program manager familiar with
 23 Mallinckrodt's suspicious order monitoring
 24 program called it the best he had ever seen?
 25 A. It would not because it doesn't

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1 relieve the responsibilities of the
 2 registrant. In my experience, there's been
 3 other matters with other registrants where
 4 there have been some comments or assessments
 5 that have proven not to be true.
 6 Q. So a company could have the
 7 best suspicious order monitoring program out
 8 there, and in your opinion, that still might
 9 not be adequate?
 10 A. No, I'm not saying that. What
 11 I'm saying is they could have the worst
 12 suspicious order system out there and because
 13 someone in the field tells them it's the best
 14 doesn't mean it's the best.
 15 Q. In general, do you think it's
 16 fair for a registrant to rely on what DEA
 17 personnel in the field say to it?
 18 A. So I want to give some
 19 qualifications to my answer. I think there's
 20 certain topics that a registrant would be
 21 comfortable with discussing with a diversion
 22 investigator and asking for guidance.
 23 I think there's other topics,
 24 especially with manufacturers and
 25 distributors, that they should -- they should

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1 or they do have knowledge that on high-level
 2 policy issues, that they would write or
 3 correspond with DEA headquarters, because my
 4 experience would indicate that most of them
 5 have in the past -- excuse me, lunch -- that
 6 most of them have in the past on a serious
 7 policy issue, have sent it in writing and
 8 requested an answer in writing.
 9 Q. Would you agree if a
 10 manufacturer requested advice in writing,
 11 that it was -- it was entitled to rely on
 12 that answer?
 13 A. If it was issued by the policy
 14 section?
 15 Q. Uh-huh.
 16 A. I think they should have some
 17 confidence in that, but as I've seen in
 18 investigating this case, even some things
 19 that come out of policy possibly are in
 20 conflict with what I was training and what I
 21 believe is the responsible actions of a
 22 diversion investigator. So generally
 23 speaking, yes.
 24 Q. And shouldn't a registrant also
 25 be entitled to rely on what they're being

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1 told by DEA personnel in the field?
 2 A. Again, I'll restate it. It
 3 depends on the topic.
 4 Q. So sometimes a registrant can
 5 rely on what DEA is telling them and
 6 sometimes they can't?
 7 A. Depending on the subject
 8 matter. For example, the correct way to
 9 initial a 222 form when it's arrived.
 10 There's some regulatory questions that are
 11 clearly spelled out in the CFR, where I could
 12 open a manual and I could tell you the
 13 content of a required record for a
 14 distribution for a C-III, what information
 15 has to be there. If the registrant would ask
 16 a question, and I could open a CFR and I
 17 could answer that.
 18 But to ask a question just
 19 about a suspicious order system, if any
 20 registrant were to ask me a question whether
 21 theirs was sufficient, I wouldn't answer that
 22 question. I'd direct them to headquarters.
 23 Q. And as you sit here today, is
 24 there any sort of guidance document a
 25 registrant can refer to so it knows when it's

<p style="text-align: right;">Page 676</p> <p>1 appropriate to rely on a DEA personnel's 2 statements and when they shouldn't? 3 A. No, sir. I would hope that 4 they would -- what they should rely on is a 5 diversion investigator having knowledge of 6 what things they can provide guidance on, 7 but, no, there's no publication that tells 8 them that. 9 Q. So it's up to the registrant to 10 figure out when they can listen to the 11 diversion investigator's advice and when they 12 shouldn't? 13 A. Well, I make that statement 14 because in my years working for diversion, 15 I've told many registrants to write 16 headquarters, and I've done cases where I've 17 reviewed letters that have been sent to DEA 18 headquarters by registrants, especially 19 distributors and manufacturers. 20 And it's my belief that they 21 may get guidance from their HDMA or HDA or 22 HD -- it changed names so much. 23 So I think it's -- there's 24 nothing in writing. There's no guidance. 25 But I think it's a well-known fact in the</p>	<p style="text-align: right;">Page 678</p> <p>1 lead Mallinckrodt to ship suspicious orders? 2 A. I think my response to that 3 would bring up that Touhy letter issue, so 4 I'm not going to answer that question, sir. 5 Q. Did you consider the portion of 6 Ms. Harper's testimony where she said 7 specifically there were times that we shipped 8 an order before the review was complete, but 9 we never shipped a suspicious order? 10 A. I don't recall reading that 11 specific statement. 12 Q. Okay. 13 A. And I'm not sure if I read it, 14 how Ms. Harper could come to that conclusion, 15 but... 16 Q. And to be clear, as we're 17 sitting here today, you aren't offering any 18 opinion one way or another on whether 19 Mallinckrodt shipped any particular 20 suspicious order, correct? 21 A. Can I get a clarification to 22 your question? Are you talking about a 23 specific order, identifying an order? 24 Q. Let's start there, yes. 25 A. No, sir.</p>
<p style="text-align: right;">Page 677</p> <p>1 distributor and manufacturer community that 2 they can seek written guidance at any time 3 from the DEA policy section, and that's based 4 on my experience. 5 Q. Okay. But in response to my 6 question, there's nothing that tells a 7 registrant when they can rely on the word of 8 a DEA diversion investigator and when they 9 cannot, correct? 10 A. No, there is not. 11 Q. On page 165 of your report, 12 discussing testimony from Karen Harper, who 13 was involved in Mallinckrodt's suspicious 14 order monitoring program, and if you look at 15 item 8, it says: Furthermore, Ms. Harper 16 admitted that Mallinckrodt did not always 17 perform due diligence on orders before 18 shipping them and that failure to conduct 19 such an investigation would lead 20 Mallinckrodt -- to Mallinckrodt potentially 21 shipping suspicious orders. 22 Do you see that? 23 A. I see that statement, yes, sir. 24 Q. Okay. And is it your opinion 25 that that lack of due diligence did, in fact,</p>	<p style="text-align: right;">Page 679</p> <p>1 Q. All right. Is it your opinion 2 today that Mallinckrodt did, in fact, ship a 3 suspicious order? 4 A. Well, in retrospect, the 5 previous question and this question again, 6 it's the Touhy letter issue comes up in 7 regards to how I could answer that question. 8 Q. Okay. But in your report in 9 this litigation, are you opining on whether 10 Mallinckrodt did, in fact, ship suspicious 11 orders? 12 A. Yes, sir. 13 Q. Can you identify any of those 14 orders? 15 A. In my report or -- 16 Q. In your report. Start there. 17 A. There's Section 14, it talks 18 about distributions to opioid products that 19 ended up in the possession of doctors that 20 were involved in -- charged and convicted 21 criminally. Based on Mallinckrodt's 22 possession of the chargeback data, I believe 23 that they had sufficient information to have 24 knowledge of that. 25 Q. But you don't identify any</p>

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1 orders submitted to Mallinckrodt that were
 2 suspicious, do you?
 3 A. In that paragraph, no, not
 4 specifically from Mallinckrodt to the doctor.
 5 Q. And you don't identify any
 6 orders that were suspicious that were
 7 submitted to Mallinckrodt anywhere in this
 8 report, correct?
 9 A. My analysis didn't look at
 10 specific orders. It looked at the -- whether
 11 or not there was a suspicious order system
 12 that met the regulatory requirements and the
 13 maintenance of effective controls.
 14 Q. A minute ago you suggested that
 15 these examples in paragraph 14 suggest that
 16 Mallinckrodt shipped suspicious orders.
 17 Did I get that right?
 18 A. Yes, sir, I did say that.
 19 Q. Okay.
 20 A. But I realized that to comment
 21 further on that, that would get back into
 22 that Touhy issue, because the link between
 23 the distributions isn't here, so I'm not
 24 going to answer that question.
 25 Q. So it's fair to say that

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1 Mallinckrodt did not ship directly to any of
 2 the individuals identified in this paragraph,
 3 right?
 4 A. Yes, sir, I don't believe they
 5 shipped directly to these doctors.
 6 Q. And so they never received an
 7 order from any of these doctors?
 8 A. I would hope if they didn't
 9 ship to them, they didn't receive an order
 10 from them. Yes, sir.
 11 Q. Correct.
 12 And in this litigation, you're
 13 not offering any opinion as to whether these
 14 individuals' purchases from others are
 15 traceable back to a suspicious order
 16 submitted to Mallinckrodt, correct?
 17 MR. FULLER: Form.
 18 A. As written today, this opinion
 19 does not describe that transaction you --
 20 that you described.
 21 BY MR. O'CONNOR:
 22 Q. And do you intend to offer at
 23 trial any opinion as to whether the product
 24 that ultimately went to these individuals was
 25 the result of a suspicious order submitted to

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1 Mallinckrodt?
 2 A. If requested by counsel, I
 3 would complete that analysis.
 4 Q. But as you sit here today, you
 5 do not have an opinion one way or another on
 6 that question?
 7 A. I have not sufficiently looked
 8 at enough data to make that conclusion, no,
 9 sir.
 10 Q. Okay. On page 166, item 11 --
 11 actually, it may begin on 165 and then go
 12 over to 166.
 13 A. Yes, sir.
 14 Q. It says: Mallinckrodt deleted
 15 questions from its distributor questionnaire
 16 regarding the distributors' monitoring of
 17 their customers.
 18 Do you see that?
 19 A. Yes, sir.
 20 Q. Do you know for sure whether
 21 Mallinckrodt deleted that question?
 22 A. This statement is based on the
 23 e-mail communication and description of that
 24 conduct. I don't believe that I had the
 25 ability to compare the form before and after

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1 to make that conclusion.
 2 Q. And you don't know, if it was
 3 deleted, for how long it was not present in
 4 the questionnaire; is that correct?
 5 A. No, sir.
 6 Q. In connection with preparing
 7 this report, did you review any shipments
 8 from Mallinckrodt into the Summit County and
 9 Cuyahoga County areas?
 10 A. Can I take a minute to look at
 11 something?
 12 Q. Very briefly. Or should we
 13 take a break? We've been going about an
 14 hour.
 15 MR. FULLER: Yeah, we can take
 16 a break. He'll check when he comes
 17 back.
 18 MR. O'CONNOR: I'll withdraw
 19 the question, but we'll come back.
 20 THE WITNESS: If you want to
 21 withdraw, we can keep going, but I
 22 just -- there's some work that's done
 23 by Dr. McCann and I would like a
 24 chance to look through it, but it's
 25 some charting that might take a little

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1 bit.
2 MR. O'CONNOR: All right.
3 We'll drop it for now and we'll decide
4 whether to come back to it. We have
5 been going about an hour, though.
6 Should we take a break?
7 MR. FULLER: Sure, quick one.
8 MR. O'CONNOR: Quick one.
9 THE VIDEOGRAPHER: Going off
10 the record, 1:57 p.m.
11 (Recess taken, 1:57 p.m. to
12 2:08 p.m.)
13 THE VIDEOGRAPHER: We're back
14 on the record at 2:08 p.m.
15 BY MR. O'CONNOR:
16 Q. Mr. Rafalski, I'd like to
17 direct your attention to page 166 of your
18 report, item number 13. In that paragraph,
19 you state that: Mallinckrodt continued to
20 ship its opioids to distributors that
21 ultimately had their licenses revoked or
22 suspended by the DEA.
23 Which distributors are you
24 referring to?
25 MR. FULLER: I'm sorry. What

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1 paragraph are you looking at, Counsel?
2 MR. O'CONNOR: 13.
3 BY MR. O'CONNOR:
4 Q. Do you recall which
5 distributors you're referring to in that
6 sentence?
7 A. Not without reviewing the
8 footnotes to ensure that I name the proper
9 one.
10 Q. Okay. And is your position
11 that it was problematic for Mallinckrodt to
12 ship opioids to those distributors simply
13 because DEA later revoked their registration?
14 A. No, I think the statement
15 means -- the statement says it was
16 problematic because they had chargeback
17 information and there was sufficient press
18 reports that would have brought it to the
19 attention of Mallinckrodt.
20 Q. In your opinion, what should
21 Mallinckrodt have done upon reviewing its
22 chargeback data with respect to these
23 distributors?
24 A. The first immediate thing it
25 would do is it would identify the distributor

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1 that's involved in that distribution, and I
2 would -- they would pay an on-site visit and
3 do an evaluation of that particular
4 distributor to make sure that it had a
5 compliant suspicious order system and
6 effective maintenance of controls.
7 Q. And is there anything else that
8 you would expect Mallinckrodt to have done
9 with respect to those distributors before the
10 DEA took action?
11 A. Well, under the maintenance of
12 effective controls, they would make a
13 notification about the potential for
14 diversion.
15 Q. A notification to --
16 A. DEA.
17 Q. -- DEA.
18 As you sit here today, are you
19 aware of whether Mallinckrodt did any of
20 those things with respect to those
21 distributors you're referring to?
22 A. I think the Touhy letter is
23 going to restrict me answering at least some
24 of the distributors I have knowledge of.
25 Q. If I were to tell you that

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1 Mallinckrodt did, in fact, audit and pay an
2 on-site visit to each of those distributors,
3 would that change your opinion?
4 MR. FULLER: Object to form,
5 vague.
6 A. No, because I'm not sure I'm
7 aware whether it was a sufficient evaluation
8 of their customers' system. I am aware --
9 strike that.
10 Because of the Touhy, I don't
11 want to make a comment on one of them.
12 BY MR. O'CONNOR:
13 Q. If I were to tell you that
14 Mallinckrodt did, in fact, inform DEA that it
15 was visiting those distributors, would that
16 change your opinion?
17 MR. FULLER: Same objection.
18 A. Just telling the DEA they
19 visited that distributor wouldn't change my
20 opinion.
21 BY MR. O'CONNOR:
22 Q. 167, item 14, you speak of
23 chargeback reports and say: While these
24 reports were used to make after-the-fact
25 determinations that their product was

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1 diverted, chargeback data was not used to
2 prevent diversion.
3 How do you expect Mallinckrodt
4 to use chargeback data to prevent diversion?
5 MR. FULLER: Counsel, you said
6 167. You mean -- it's at 166?
7 MR. O'CONNOR: It might
8 actually be 160- --
9 MR. DAVISON: At the bottom --
10 it's the bottom of number 14, 167.
11 THE WITNESS: Okay, over on the
12 other page. I'm sorry.
13 MR. FULLER: Okay. Both pages.
14 Sorry, didn't mean to interrupt.
15 A. I believe the chargeback data
16 can be incorporated into a suspicious order
17 monitoring system.
18 BY MR. O'CONNOR:
19 Q. And you believe that it can
20 somehow be used to prevent diversion?
21 A. Oh, yes, sir.
22 Q. Earlier you testified that
23 chargeback data might not even be received
24 until 30 days after the fact, correct?
25 A. Yes. But I still believe no

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1 matter when it's received, it can be utilized
2 in a suspicious order monitoring system to
3 prevent diversion.
4 One example -- one good example
5 for chargebacks is the identification of a
6 pharmacy that would be purchasing the same
7 product by Mallinckrodt, or a highly abused
8 product by Mallinckrodt and ten pharmacies --
9 or, I mean, one pharmacy from maybe ten
10 distributors in large amounts.
11 Q. But you would agree with me
12 that by the time Mallinckrodt learns of a
13 purchase by the pharmacy, that pharmacy has
14 already obtained the product, correct?
15 A. Yeah, but I don't think your
16 question or my statement is time sensitive.
17 It's when the -- it's when the registrant
18 knows or learns of it. That's when I think
19 it has a responsibility to take action.
20 I don't think it's just
21 dependent on whether they could know it in a
22 realtime or whether it's immediately upon
23 shipped. I think there's all kinds of
24 information that comes in, relevant
25 transaction data, that could lead a

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1 registrant to identify diversion.
2 Q. But again, by the time
3 Mallinckrodt learns of a transaction to one
4 of the pharmacies that you mentioned that
5 might raise concern, that pharmacy already
6 has the product, correct?
7 A. Yes, that's --
8 Q. And -- thank you.
9 A. Well --
10 MR. FULLER: Go ahead and
11 finish your answer.
12 A. That is a true statement, but
13 the issue at hand is that diversion is
14 occurring and then they gained knowledge of
15 it. It's not dependent on how long it took
16 them to know or if there's delay in them
17 receiving the information. It's when they
18 actually have knowledge that it occurred.
19 BY MR. O'CONNOR:
20 Q. When you say they have
21 knowledge that diversion is occurring, do you
22 mean that a pharmacy is purchasing a large
23 amount of product?
24 A. It could be that. It could be
25 the other circumstance that I described to

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1 you, multiple distributors. There's other
2 factors that chargeback could lead you to.
3 They also would be able to look at a
4 geographic location through chargeback, so
5 they may identify a small rural area in
6 Florida where there's three or four
7 pharmacies that are getting a large amount
8 from multiple distributors. So there's -- in
9 different distributors.
10 So there's other factors, but
11 it's just not time sensitive.
12 Q. But you would agree with me
13 that you can't conclude simply from the
14 volume a pharmacy is purchasing that
15 diversion is, in fact, occurring there,
16 correct?
17 A. I think there are some extreme
18 cases where you could make that opinion just
19 based on volume.
20 Q. Fair to say in the vast
21 majority of cases you are not able to tell
22 simply by looking at volume whether diversion
23 is taking place?
24 A. I'm not sure I like the term
25 "vast majority." I would say it's more

<p style="text-align: right;">Page 692</p> <p>1 likely than not, but it occurs more 2 frequently now than it ever has. 3 Q. How much oxycodone would a 4 pharmacy have to purchase for you to conclude 5 that it's diverting oxycodone? 6 A. I'd have to see their customer 7 file and what their scope of business, who 8 they're supplying to be able to make that 9 determination. There's not just a -- 10 Q. And that's because you cannot 11 determine whether diversion is occurring 12 simply by looking at the volume, correct? 13 A. That's not correct. So if we 14 look at a pharmacy with a population of 1,000 15 people and there's a million pills go 16 there -- and that's an extreme case, but I 17 think I could clearly say there's something 18 occurring, diversion's occurring there. 19 If it's an amount that's not 20 consumable by that geographic area, I would 21 say it's very likely that there's diversion 22 occurring. 23 Q. Outside of this extreme case 24 that you mention where there's a population 25 of 1,000 getting a million pills, fair to say</p>	<p style="text-align: right;">Page 694</p> <p>1 Q. With respect to your review of 2 manufacturers' suspicious order monitoring 3 programs, what methodology did you apply in 4 coming to your opinions? 5 A. The one that was identified or 6 the lack of one that was identified by each 7 manufacturer. 8 Q. But what methodology did you 9 apply when assessing the suspicious order 10 monitoring programs? 11 A. Well, I would apply my 12 training, experience, knowledge in doing 13 these kinds of cases, in regards to what I -- 14 was provided to me to make judgment and form 15 an opinion. 16 Q. And when you say "provided to," 17 you mean by plaintiffs' counsel? 18 A. No, by -- in discovery. 19 Q. And you received that 20 discovery -- those discovery materials 21 through plaintiffs' counsel, correct? 22 A. Yes, but at my direction of 23 what documents I wanted to see. I know we'll 24 get back to the -- 25 Q. So you --</p>
<p style="text-align: right;">Page 693</p> <p>1 that a manufacturer can't tell if the 2 diversion is occurring simply by looking at 3 the volume of a purchase? 4 A. Are you saying that if they saw 5 that situation, they would say that diversion 6 is occurring and then outside of that 7 situation? I think generally speaking, just 8 looking at volume of a pharmacy, I think they 9 would have sufficient data. 10 So let's say, for example, 11 Mallinckrodt, they distribute to many 12 distributors who then distribute to many 13 pharmacies, so I think they have established 14 a pretty good baseline of what a usual order 15 is. So I think they would identify some 16 pharmacies by volume that would rise to a 17 level of suspicion. 18 I would agree -- generally 19 agree that in most cases the amount of the 20 drug alone wouldn't immediately make them 21 suspicious -- say that that is a suspicious 22 order, but I think there is a point or a 23 volume where it's very likely that is going 24 to occur. Florida would be an example of 25 that.</p>	<p style="text-align: right;">Page 695</p> <p>1 A. -- the, you know, whether 2 everything was provided to me, but my opinion 3 is based on -- which I believe is everything 4 that was available and the topics I 5 requested. 6 Q. Okay. So your opinion is based 7 solely on your review of the documents that 8 you received and that -- and your experience; 9 is that fair? 10 A. Experience and training, yes, 11 sir. 12 Q. Okay. 13 A. And legal guidance. 14 Q. From plaintiffs' counsel? 15 A. No, from my employment with the 16 DEA. 17 Q. So your own legal opinions? 18 A. No, receiving legal guidance 19 from lawyers. 20 Q. Okay. At DEA? 21 A. Yes, sir. 22 Q. Okay. Are you familiar with 23 Scott Higham? 24 A. The Washington Post reporter? 25 Q. Yes.</p>

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1 A. Yes, sir.
2 Q. Have you ever had a
3 conversation with Scott Higham?
4 A. Yes, sir.
5 Q. How many times?
6 A. I don't know, four or five.
7 Q. What was the substance of those
8 communications?
9 A. Initial were he was writing an
10 article about the DEA and the new -- I think
11 it was a regulation or change in the law --
12 change in regulation or law which was in
13 regards to when a registrant sees some
14 adverse or administrative action, they get to
15 do a correction plan. And I think he wanted
16 me to make some comments on that, so I
17 provided some comments I believe that he
18 published in an article.
19 Q. Did you ever discuss
20 Mallinckrodt with Scott Higham?
21 A. I believe I probably did,
22 postsettlement.
23 Q. When was your first
24 conversation with Mr. Higham?
25 A. I don't recall.

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1 Q. Were you still at DEA?
2 A. No, sir.
3 Q. After you left DEA?
4 A. Yes, sir.
5 Q. Did you ever provide Mr. Higham
6 or anyone else at The Washington Post with
7 any documents?
8 A. No, sir. Not that I recall,
9 no, sir.
10 Q. Aside from any discussions you
11 had with Mr. Higham, did you have any
12 conversations with Mr. Lenny Bernstein?
13 A. The first time I met Mr. Higham
14 he was present, but these weren't really
15 discussions about any relevant -- it was a
16 beer at a rooftop of a hotel or restaurant.
17 He was introduced to me, but that would be my
18 extent of my conversations with him.
19 Q. Aside from Mallinckrodt, did
20 you ever discuss any other defendant in this
21 case with Mr. Higham or Mr. Bernstein?
22 A. No, I don't believe I did.
23 Q. Have you ever had any
24 discussions with individuals associated with
25 60 Minutes?

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1 A. Yes, sir.
2 Q. How many discussions did you
3 have with folks at 60 Minutes?
4 A. Probably more than ten.
5 Q. Okay.
6 A. I don't know exactly, but --
7 Q. Did any of those discussions
8 relate to Mallinckrodt?
9 A. Yes, sir.
10 Q. And what was the substance of
11 those conversations?
12 A. The case against Mallinckrodt,
13 the information that -- in regards to the
14 actions of Mallinckrodt.
15 Q. Did you receive Touhy
16 authorization before disclosing any of
17 those --
18 A. No, sir.
19 Q. -- that information?
20 Did you clear any of the
21 discussions with the Department of Justice in
22 any form before talking to 60 Minutes?
23 A. No, sir.
24 Q. What information did you share
25 with respect to Mallinckrodt?

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1 A. I believe it was information
2 that would be readily available, the -- I
3 think the memorandum of agreement might have
4 been online at that time, some general
5 description of the distributions and the
6 pharmacies.
7 60 Minutes already had some
8 information. There were some leaked
9 documents by somebody, so they asked me
10 questions about that information, but...
11 Q. Did you provide any documents
12 to 60 Minutes?
13 A. You know, I took a -- I created
14 a couple of charts and a graph and -- I
15 don't -- I believe that I might have gave
16 those to them, but I'm not positive.
17 Q. Okay.
18 A. One of the charts -- you want
19 me to explain?
20 Q. Yes, please.
21 A. So there was a chart that
22 involved distributions to doctors in all the
23 states of the United States. There was a
24 chart on the number of pharmacies and
25 distribution to the pharmacies in the United

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1 States, and I think there was one graph of
 2 the distribution of Mallinckrodt product
 3 from -- to the United States and to the state
 4 of Florida.
 5 MR. O'CONNOR: Counsel, I'm
 6 just going to say on the record, we're
 7 going to want copies of those
 8 documents.
 9 BY MR. O'CONNOR:
 10 Q. Do you still have them in your
 11 possession?
 12 A. I think I do. I don't have
 13 them today, but I believe --
 14 Q. Okay.
 15 A. -- that I have them at home,
 16 but I'm not positive.
 17 Q. Did you receive any
 18 compensation in connection with your
 19 discussions with either 60 Minutes or The
 20 Washington Post?
 21 A. No, sir.
 22 Q. Did you discuss any other
 23 defendants besides Mallinckrodt with
 24 60 Minutes?
 25 A. I don't believe so, no, sir.

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1 Q. You mentioned that 60 Minutes
 2 had access to certain documents related to
 3 Mallinckrodt; is that correct?
 4 A. I believe both 60 Minutes and
 5 The Washington Post, I think they wrote an
 6 article about the document.
 7 Q. Okay. Do you know how they
 8 obtained those documents?
 9 A. No, but I wish I did.
 10 Q. Why do you say that?
 11 A. Well, it was a sensitive
 12 document during the time I was conducting an
 13 investigation, and that would be the main
 14 reason. And second reason would be I think
 15 it was not totally accurately described.
 16 Q. What was in the -- what was
 17 disclosed publicly in the media was not an
 18 accurate reflection of what was in the
 19 document?
 20 A. No, it was an internal
 21 document, and so it was one of the documents
 22 that I had privy to, so obviously it's
 23 concerning. I didn't release it, but it
 24 wasn't -- well, I guess when you have a
 25 document and others have a document, there's

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1 no way to know who has access to it, but just
 2 the mere fact that somebody would give a
 3 document out during -- while an ongoing case.
 4 Q. Because that would be
 5 prohibited by Department of Justice rules?
 6 A. Sure. Yes, sir.
 7 Q. And just getting back to my
 8 earlier question, is your testimony today
 9 that what was reported in the media with
 10 respect to those documents did not accurately
 11 reflect some of the content?
 12 A. Well, I think they made some
 13 opinions about the -- what was going on with
 14 the case or whether people were happy or
 15 unhappy. I don't know that they were
 16 specifically directed at me, but just
 17 generalized statements that I don't think
 18 were accurate.
 19 Q. Okay. So --
 20 A. And I thought it may
 21 influence -- the case was -- I wouldn't
 22 say -- there was ongoing discussions in that
 23 case, and I had concern that it would affect
 24 that.
 25 Q. You were concerned that the

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1 statements in the media may influence the
 2 case?
 3 A. Not so much the case, because
 4 the facts of the case were the facts. That
 5 it might influence the relationship between
 6 the people that were discussing the case.
 7 MR. O'CONNOR: So I'm going to
 8 make the same speech my colleagues
 9 have. There are many more questions
 10 I'd like to ask and we have not had
 11 enough time to do it, so I'm going to
 12 reserve my right to resume this
 13 questioning and ask additional
 14 questions, but out of respect for my
 15 codefendants here, I'm going to pass
 16 the mic so we can go off the record.
 17 THE VIDEOGRAPHER: Off the
 18 record at 2:28 p.m.
 19 (Recess taken, 2:28 p.m. to
 20 2:30 p.m.)
 21 THE VIDEOGRAPHER: We're back
 22 on the record at 2:30 p.m.
 23 EXAMINATION
 24 BY MS. LUCAS:
 25 Q. Good afternoon, Mr. Rafalski.

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1 I'm Amy Lucas. I represent Johnson & Johnson
 2 and Janssen.
 3 A. Good afternoon.
 4 Q. Good afternoon.
 5 I have a very short amount of
 6 time to ask you questions.
 7 A. Okay.
 8 Q. So I'm going to do my best to
 9 ask you a lot of yes-or-no questions, so I'm
 10 going to ask that you give me a yes-or-no
 11 answer so that we can get this over with as
 12 quickly as possible. Can you do that?
 13 A. Well, if it's possible to
 14 answer a yes or no.
 15 Q. Sure.
 16 And I also ask if you don't
 17 understand something that I've asked, ask me
 18 to clarify it --
 19 A. Okay.
 20 Q. -- and I'll clarify it. If you
 21 answer it though, I will assume that you
 22 understood.
 23 A. I understand.
 24 Q. Great.
 25 It says in your report that you

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1 reviewed documents identified in Schedule I,
 2 correct? It's on page 7. To be specific, "I
 3 have also reviewed documents identified in
 4 the attachment Schedule I."
 5 A. Which paragraph are you
 6 speaking on page 7?
 7 Q. Yes, on page 7 at the bottom,
 8 very last sentence.
 9 A. Yes.
 10 Q. Okay. You said earlier that
 11 other than your training and experience, the
 12 documents and testimony cited in the
 13 footnotes in your report provide the specific
 14 support for those opinions, correct?
 15 MR. FULLER: Object to form,
 16 same basis as earlier.
 17 A. Yes, I would agree with that
 18 statement.
 19 BY MS. LUCAS:
 20 Q. How long did you spend
 21 reviewing the Janssen evidence cited in
 22 Schedule I?
 23 A. I don't recall.
 24 Q. Did you see -- did you ask to
 25 see any documents other than what's in the

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1 report or Schedule I for Janssen?
 2 A. I have a recollection I may
 3 have looked in some of the discovery material
 4 for other documents, but specifically, I
 5 don't recall which documents.
 6 Q. What types of documents from
 7 Janssen did you believe you needed to see in
 8 order to form your opinions in this case?
 9 A. Communications among employees,
 10 I believe I looked for, or -- and I think I
 11 looked for, just my recollection, maybe due
 12 diligence materials.
 13 Q. Did you find any communications
 14 among employees or due diligence materials?
 15 A. Not that caused me to place
 16 those in my report.
 17 Q. But you did find some?
 18 A. I don't recall. General
 19 recollection, I believe I saw some
 20 communications, but I'm not positive.
 21 Q. Did you believe that you didn't
 22 need to include those in the report?
 23 A. Well, I don't -- just my
 24 recollection, I don't -- I don't believe that
 25 they would have had any impact, positive or

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1 negatively, on the matter I was tasked to
 2 make comment on.
 3 Q. For Janssen, what was the
 4 matter you were asked to make comment on?
 5 A. Whether or not they had a
 6 sufficient -- a sufficient suspicious order
 7 system and whether they had an effective
 8 maintenance of -- effective maintenance of
 9 controls in place.
 10 Q. And you believed that it was
 11 not necessary to consider Janssen's due
 12 diligence materials in coming to a conclusion
 13 for that?
 14 A. Oh, I don't think I said that.
 15 Q. You said: I don't believe that
 16 they would have had any impact, positive or
 17 negatively, on the matter I was tasked to
 18 make comment on.
 19 A. Only on those documents which I
 20 found or reviewed.
 21 Q. I see.
 22 Were there additional documents
 23 you would have found useful?
 24 A. I don't know if they exist or
 25 not. During my search, I did not find them.

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1 Q. Did you ask anybody to help you
2 locate them?

3 A. I didn't make that specific
4 request, but part of my communication of the
5 documents I needed to make my opinion were
6 those documents. I was hoping they were all
7 there, but I also made -- I recall making a
8 search on my own looking for documents.

9 Q. So it's correct that you did
10 not make a specific request for Janssen due
11 diligence materials; is that right?

12 MR. FULLER: Object to form.

13 A. That's not an accurate
14 statement. I made a request for specific
15 types of documents to formulate my opinion
16 that would be relative to all the
17 manufacturers. So just so I understand your
18 question, it wasn't specific to Janssen. It
19 was these would be the documents I would not
20 want to see, and so I -- my expectation was
21 it would apply to all the manufacturers.

22 BY MS. LUCAS:

23 Q. Did you say I would not want to
24 see or I want to see?

25 A. No, I want to see. I'm sorry.

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1 I misstated if I said that.

2 Q. What types of documents did you
3 tell counsel that you would want to see,
4 other than communication among employees and
5 due diligence materials?

6 A. Any due diligence materials,
7 any policies related to suspicious order
8 systems, any communications -- well, I think
9 you said that, not those -- communications
10 related to those topics, any studies
11 conducted by outside consultants or
12 consultant agencies, any information that
13 would confirm the existence of chargeback
14 data, IQVIE data -- IQVIA data, I'm sorry.

15 I don't know if that's the
16 complete list, but that's a general idea of
17 the type of documents I would request. And
18 also I asked for some guidance too in the
19 depositions that would be more indicative of
20 that information.

21 Q. You asked to be guided towards
22 the depo testimony that would bear on those
23 issues; is that right?

24 A. Yes. And in some cases even
25 the specific areas to start with.

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1 Q. Did anybody else write any
2 portion of the Janssen opinion in your
3 report?

4 A. This is my report. As I've
5 stated earlier, they might provide me with
6 a -- not an analysis, but a description of
7 some of the material, so I would take the
8 information, check the section of the
9 deposition or the footnote material or the
10 reference they provided me.

11 I may redraft it, edit it,
12 change it.

13 Q. Let me ask that again.
14 Yes or no, did anybody write
15 any portion of the Janssen opinion in your
16 report?

17 A. No, this is my report. I wrote
18 it.

19 Q. Did they write any first draft
20 of the opinion about Janssen in your report,
21 yes or no?

22 A. Draft, no. Might they have
23 provided me with some descriptions of some
24 sections, but I wouldn't consider that a
25 draft of my report, no.

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1 Q. A description of a section is
2 not a draft?

3 A. Well, I guess you need to
4 provide me with what your description of --
5 or a definition of what a draft is. If they
6 provided me a sentence and told me here's the
7 reference document, and the sentence
8 accurately described it, I may change it, I
9 may not change it. I may edit it. But --
10 and there's a possibility I may use it.

11 Q. So you cannot say that you
12 wrote 100% of this report about Janssen
13 without any input from plaintiffs' counsel,
14 correct?

15 A. That's correct.

16 Q. Did you personally review all
17 of the Janssen materials cited in your report
18 footnotes, yes or no?

19 A. Yes, I believe I did.

20 Q. Okay. I'd like to put your
21 report aside for a moment because at trial
22 that's not coming in, and I want you to
23 summarize for me your opinions about Janssen.

24 MR. FULLER: You can use your
25 report.

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1 BY MS. LUCAS:
 2 Q. Well, first I want to ask, can
 3 you do it without referencing your report?
 4 A. No, because of the content and
 5 all the different distributors and
 6 manufacturers, they all start to blend
 7 together, so to just give you a generalized
 8 statement and opinion, I'd be reluctant to do
 9 that because -- and plus, the fact that I've
 10 went over them for the last 12 hours, I
 11 couldn't accurately just do that off the top
 12 of my head.
 13 MR. FULLER: For the record,
 14 the report is 187 pages and cites
 15 thousands of documents. The witness
 16 is not going to put aside his report.
 17 BY MS. LUCAS:
 18 Q. But the Janssen part is only
 19 four pages. So if you can turn to the
 20 Janssen part, since we need to refresh your
 21 recollection. I don't need you to review the
 22 entire thing, unless you'd like to go off the
 23 record, in which case I'm happy to.
 24 MR. FULLER: We'll do it on the
 25 record.

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1 BY MS. LUCAS:
 2 Q. But if you'd like to take a
 3 look at that and if that refreshes your
 4 recollection about what your opinions are
 5 about Janssen, I'll wait.
 6 A. I just read it into the record?
 7 It's written at the conclusion --
 8 Q. Oh, no, no need, because I want
 9 to know what you're going to say at trial.
 10 A. General statement, I'm going to
 11 say that they had insufficient suspicious
 12 order system, that it didn't look at all of
 13 the factors required as stated in the
 14 regulation. It only looked at size, unusual
 15 size; did not look at frequency and pattern.
 16 Q. Okay. So you have references
 17 in your report to the realtime portion of the
 18 suspicious order monitoring system. Is your
 19 report an evaluation of Janssen's entire SOMS
 20 program or the realtime portion?
 21 A. Could you explain what you mean
 22 by realtime?
 23 Q. Well, I was going to ask you
 24 that. So if you turn to page 160,
 25 paragraph 8 -- or here, paragraph 4 at the

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1 top. Janssen only monitored for orders of
 2 unusual size and failed to ever monitor for
 3 frequency and/or pattern in realtime.
 4 And then other parts of your
 5 report consistently reference realtime, and
 6 what I wanted to know is what you mean when
 7 you say realtime suspicious order monitoring
 8 system.
 9 A. Realtime would measure orders
 10 that were in realtime, that were occurring
 11 and were in -- being ordered and then being
 12 prepared for shipment. Those are realtime
 13 orders.
 14 An example of a nonrealtime
 15 order would be potentially some chargeback
 16 data that would be received after the
 17 distribution. IQVIA would be after -- not a
 18 realtime, but it would be post-distribution.
 19 Q. Does the due diligence -- well,
 20 strike that.
 21 You understand that Janssen's
 22 system had an algorithm, correct?
 23 A. Yes.
 24 Q. And the algorithm flagged
 25 potentially suspicious orders based on the

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1 formula, correct?
 2 A. Yes, sir -- yes, ma'am. Sorry.
 3 Q. That's okay.
 4 After the flagged -- the order
 5 was flagged, you understand that there was a
 6 due diligence process that took place,
 7 correct?
 8 A. My recollection is there was
 9 some due diligence, but it was insufficient.
 10 Q. What is that recollection based
 11 on?
 12 A. My recollection of reviewing
 13 documents and reviewing specifically
 14 Ms. Dempsey's deposition.
 15 Q. Did you review the entirety of
 16 Ms. Dempsey's deposition? Strike that, I'm
 17 sorry.
 18 Ms. Dempsey is whom, to your
 19 understanding? I'm not asking for an exact
 20 title or role.
 21 A. I think she's a director of
 22 compliance, but I think she may have held
 23 another title. My recollection, she might
 24 have had during her employment, it was more
 25 than just that title. She may have another

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1 title or a different position.
2 Q. You understand that she
3 provided testimony regarding Janssen's
4 suspicious order monitoring system, correct?
5 A. Yes, ma'am.
6 Q. Now, did you review all of
7 Ms. Dempsey's deposition transcript?
8 A. Yes, I did.
9 Q. Both volumes?
10 A. Yes.
11 Q. Did you review all of the
12 exhibits?
13 A. Yes.
14 Q. Personally?
15 A. Yes.
16 Q. And why then are not all of
17 those exhibits in your Schedule I?
18 MR. FULLER: Object to form.
19 That misstates his schedule. He cites
20 her deposition as well as the
21 exhibits, so it's cited. We did not
22 go through and list them individually.
23 MS. LUCAS: Just -- I'll wait
24 for him to answer. You can answer.
25 A. I reviewed them, and they were

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1 used to formulate my opinion, but I just
2 didn't list each one individually in the
3 report.
4 BY MS. LUCAS:
5 Q. So when you say realtime
6 suspicious order monitoring system, you're
7 talking about Janssen's algorithm and the due
8 diligence process; is that correct?
9 A. Well, the due diligence -- no.
10 So the due diligence doesn't necessarily mean
11 in realtime, so there's due diligence that
12 would be conducted as part of your
13 maintenance of effective controls.
14 Q. Let me back up then.
15 When you say realtime
16 suspicious order monitoring system, you're
17 talking about the algorithm and then the due
18 diligence that occurs prior to shipment of an
19 order that had been flagged?
20 A. Yes, ma'am.
21 Q. Got it.
22 Now, a suspicious order
23 monitoring system can also include
24 post-shipping diligence that you were just
25 referencing, right?

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1 A. Say that again one more time.
2 Q. A suspicious order monitoring
3 system can also include post-shipping due
4 diligence that you were just referencing?
5 A. It could, yes.
6 Q. Did you consider any
7 post-shipping due diligence that Janssen did?
8 A. I don't have a recollection if
9 I did or not.
10 Q. And I have a quick question
11 before we move on.
12 You said that chargeback data
13 and IQVIA data are not realtime, correct?
14 A. My experience in conducting
15 investigations, I would make the statement
16 that it's -- because it's a secondary
17 distribution and the dispensing is a
18 secondary action. It would only be direct
19 information if it was a direct distribution
20 to a pharmacy, but then it wouldn't be
21 chargeback. It would be an order.
22 So, yes, that's the reason it's
23 realtime.
24 Q. Wait. You just -- now it's
25 realtime?

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1 A. No, it -- it would not be
2 realtime.
3 Q. Okay.
4 A. The transaction -- there would
5 be no chargeback if they distributed directly
6 to a pharmacy.
7 Q. And yes or no, do you believe
8 that IQVIA data and chargeback data can
9 nevertheless be incorporated into a realtime
10 suspicious order monitoring system?
11 A. Yes, I believe it could. I
12 think it could -- it could provide -- even
13 though it's post-data, I think historically
14 it could provide some averages and levels and
15 conduct that could be used in a suspicious
16 order monitoring system.
17 Q. You said that Janssen only
18 monitored for orders of unusual size and
19 failed to ever monitor for frequency and/or
20 pattern in realtime.
21 Can you very succinctly explain
22 what you mean by "pattern"?
23 A. Well, there's many different
24 aspects to the pattern. Regulations says
25 substantially deviating.

<p style="text-align: right;">Page 720</p> <p>1 So succinctly, how drugs are 2 ordered, so how would be the -- how they're 3 grouped. So say, for example, a customer is 4 ordering drugs in -- they generally in my 5 experience order drugs in just certain 6 patterns, certain groups, ten to an order 7 form, variety of types. One pattern could be 8 all of a sudden one particular drug is 9 showing up on one order form, just one drug. 10 That could be a pattern.</p> <p>11 Another pattern -- excuse me -- 12 could be the type of drug, so there could be 13 a shift in the pattern. For example, 14 oxycodone, there's many different kinds of 15 oxycodone. So if you're not looking 16 specifically to a product, there could be an 17 increase in a pattern of one particular drug 18 within a family.</p> <p>19 Specifically looking at for a 20 highly abused drug, for example, oxy 30 or a 21 drug the registrant would know is highly 22 abused, that could be another example.</p> <p>23 Q. Could dosage? 24 A. Dosage, you mean the size of 25 the bottle?</p>	<p style="text-align: right;">Page 722</p> <p>1 ma'am, that it didn't differentiate specific 2 drugs by NDC.</p> <p>3 Q. And if the algorithm did 4 differentiate among NDC codes, you'd need to 5 revise your opinion, correct? 6 MR. FULLER: Object to form, 7 lack of clarity. 8 BY MS. LUCAS: 9 Q. Well, if that statement is 10 inaccurate, I wouldn't want an inaccurate 11 opinion. So if it was brought to my 12 attention, I think I would be bound to 13 correct it. 14 BY MS. LUCAS: 15 Q. What did you mean by "for drugs 16 with a higher risk of diversion"? Higher 17 than what? 18 A. Well, the higher risk means 19 that those are drugs that are more frequently 20 targeted by diversion. Prime example would 21 be the oxycodone 30-milligram at this current 22 time. 23 Q. Well, Janssen doesn't sell 24 oxycodone 30, so for Janssen, higher than 25 what?</p>
<p style="text-align: right;">Page 721</p> <p>1 Q. Yeah, milligrams, micrograms. 2 A. Sure, that would be a different 3 drug. So you would focus on first the highly 4 abused drugs within the family. Your 5 30-milligram oxycodones, your 10-milligram 6 oxycodones are two of the first before you 7 would look at the others. They're all 8 relevant because they all could be diverted, 9 but those would be just a couple of examples.</p> <p>10 Q. Do you -- you said that 11 Janssen's suspicious realtime order 12 monitoring system did not utilize any 13 downstream customer information available and 14 did not differentiate among NDC codes for 15 drugs with a higher risk of diversion. 16 Yes or no, is it your 17 understanding that Janssen's algorithm did 18 not monitor different NDC codes? 19 MR. FULLER: Object to form. 20 BY MS. LUCAS: 21 Q. I'm at page 162. 22 A. Yeah, I wanted to look at an 23 earlier statement I made. 24 (Document review.) 25 A. That's my statement, yes,</p>	<p style="text-align: right;">Page 723</p> <p>1 A. Hydrocodone 10-milligram 2 products. 3 Q. Okay. They also don't sell 4 those. So I'm trying to understand what -- 5 what Janssen should have understood this term 6 to mean, "NDC codes for drugs with a higher 7 risk of diversion." 8 A. I think my reference there was 9 the fentanyl products, the Duragesic patches. 10 Q. You said earlier that it's 11 DEA's job to enforce the Controlled 12 Substances Act, which it's been delegated 13 that authority by Congress, right? 14 A. Well, yes, but I think more 15 specifically by the Attorney General. 16 Q. Fair. 17 One way -- and then the 18 Attorney General has tasked -- 19 A. Delegated it to the DEA, yes, 20 ma'am. 21 Q. Okay. The DEA then in turn 22 enforces the CSA and it's implementing 23 regulations by conducting field inspections 24 or audits, right? 25 A. Could you read that back?</p>

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1 Q. The DEA --
2 A. Or restate it, I'm sorry.
3 Q. Yeah. The DEA, one of the
4 things it does to enforce the CSA and the
5 implementing regulations, is conduct field
6 inspections or audits of manufacturers,
7 right?
8 A. That's one of the activities
9 they do to ensure that registrants are
10 compliant with the Code of Federal
11 Regulations and the CSA, yes, ma'am.
12 Q. Another word for those would be
13 diversion inspections?
14 A. I've never heard that specific
15 term, but they're called all kinds of things
16 so --
17 Q. What do you call them?
18 A. Usually it's either a
19 regulatory investigation or a work plan
20 investigation. A work plan is defined as
21 they come out on October 1st and they are
22 assigned during the work plan year of the
23 DEA, October 1st to September 30th.
24 Q. How many -- are those
25 synonymous, regulatory investigation and work

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1 plan investigation?
2 A. You could see either one
3 utilized by the DEA. I think it's probably
4 on their website or readily available for a
5 person to find.
6 Q. If I say a field inspection,
7 you would understand that that also means --
8 A. Wouldn't mean the same to me.
9 When you use the word "inspection," you know,
10 there's a form we use, an 82, which is a
11 voluntary compliance to an inspection. So
12 you would use that form in a lot of different
13 purposes.
14 So I'm -- I wouldn't
15 automatically assume that's a regulatory
16 investigation.
17 Q. A regulatory investigation
18 happens, you said, once a year?
19 A. It's up to the management when
20 they assign them. Typically between every
21 three to five years for certain types of
22 registrants, maybe longer for others, just
23 generally speaking.
24 Q. And when would a Form 82 be
25 used?

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1 A. Anytime I went to a registered
2 location, before I look at required
3 documents, a registrant has to give me
4 approval to use that form and sign it and
5 voluntarily approve, or I could not look at
6 the required records or make an inspection on
7 the premises.
8 Q. Now, a form -- I'm trying to
9 understand the world -- define the world that
10 we're living in.
11 A. I'm going to answer but I'm
12 going to be careful about that Touhy letter.
13 Q. I understand.
14 The regulatory investigations,
15 how long do those typically last once they're
16 initiated? A couple days?
17 A. Well, they could be as quick as
18 a half a day or there's been some
19 circumstances where I've spent the better
20 part of a month or more.
21 Q. So three days is not unusual
22 for a regulatory investigation?
23 A. Depending on the type of
24 registrant, it may not be unusual. But it's
25 all dependent on what type of registrant.

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1 Q. How many regulatory
2 investigations have you participated in, or
3 conducted? Strike that.
4 How many regulatory
5 investigations for the DEA have you conducted
6 of manufacturer defendants -- or
7 manufacturers?
8 A. Manufacturers?
9 Q. Sure. Yes.
10 A. I don't recall, but I would say
11 definitely less than ten, maybe between five
12 and ten, just because it was a long career.
13 And when you say that I may be
14 on-site with somebody else as the lead, we go
15 in twos, so there would be my investigations
16 that are assigned to me, but I could have
17 been present at one that was somebody else's.
18 Q. Can you please give me a list
19 of the things that you ask for when you
20 conduct a regulatory investigation?
21 A. I don't have a list with me.
22 There's really not a list that exists.
23 Q. What are you looking for?
24 A. I'm going to look for --
25 MR. FULLER: Object to form,

<p style="text-align: right;">Page 728</p> <p>1 and I warn you on your Touhy. 2 Anything that's generally not known to 3 the public is beyond your 4 authorization. 5 A. I'm not aware that's -- I'm not 6 aware that that information is publicly 7 available, but I've never tried to see if I 8 could Google that. But I -- now that I'm 9 aware of it, I probably will not answer that 10 question. 11 MS. LUCAS: We'll reserve our 12 rights on that. 13 THE WITNESS: Okay. 14 BY MS. LUCAS: 15 Q. Are you familiar with the 16 acronym SOP? 17 A. Yes, standard operating 18 procedure. Yes, ma'am. 19 Q. During a regulatory 20 investigation, is it common for the DEA to 21 review the registrant's SOPs for their 22 suspicious order monitoring system? 23 A. I don't know if the Touhy -- 24 thinking about the Touhy, I'm not sure I 25 should answer that question.</p>	<p style="text-align: right;">Page 730</p> <p>1 all diversion investigators, so I don't know. 2 Q. Fair. In your experience? 3 A. Yes. 4 Q. Now, during these regulatory 5 investigations, if the DEA in your experience 6 had concerns about a manufacturer's 7 suspicious order monitoring program that they 8 observed during the inspection, the DEA would 9 raise those concerns with the registrant, 10 right? 11 MR. FULLER: Object to form. 12 Again, it goes to DEA's policy 13 on investigations and their position 14 and what they raise and what they 15 don't raise, so I would say that's 16 outside of your Touhy authorization, 17 Mr. Rafalski. 18 THE WITNESS: I'd agree with 19 that. I'm not going to answer based 20 on the Touhy letter. 21 BY MS. LUCAS: 22 Q. You can't tell me whether in 23 your experience if there were concerns about 24 a suspicious order monitoring program that 25 you observed during a regulatory</p>
<p style="text-align: right;">Page 729</p> <p>1 Q. What are we doing here? Are 2 you saying that you're doing something 3 here -- you reviewed SOPs for this report, 4 correct? 5 A. Yeah, but not in the capacity 6 as a diversion investigator. 7 Q. Are you saying that you're 8 doing something in this report that you would 9 not have done as a diversion investigator? 10 MR. FULLER: Object to form. 11 That wasn't the question you asked. 12 A. No, I think you're asking me to 13 comment on my actions that I would conduct at 14 a registrant's location as a diversion 15 investigator, and I'm not sure that that 16 conduct would be readily available, unless I 17 misunderstood your question. 18 BY MS. LUCAS: 19 Q. I'm not -- I just want a yes or 20 no, whether it's common for DEA investigators 21 to ask for SOPs during a regulatory 22 investigation. 23 A. I don't -- I don't know. 24 Q. In your experience. 25 A. I don't know what's common for</p>	<p style="text-align: right;">Page 731</p> <p>1 investigation, whether you would raise those 2 with the registrant? 3 MR. FULLER: Same objection and 4 instruction. Point out to counsel 5 that we have a 30(b) of the DEA on 6 Friday and you can ask the question. 7 THE WITNESS: I'm not going to 8 answer the question because of the 9 Touhy. 10 BY MS. LUCAS: 11 Q. Well, are you aware that 12 Mr. Prevoznik has testified that if the DEA 13 has concerns about a registrant's suspicious 14 order monitoring written policies, it would 15 raise those concerns with the registrant? 16 A. I would -- I would either not 17 be surprised or not surprised that he raised 18 those concerns, but I believe he would be, in 19 his position, in a better position to be able 20 to know whether to release that information 21 and the public availability. I don't. Or 22 whether he has a Touhy authorization to speak 23 to that or not. 24 Q. Well, you're not telling me 25 that if a DEA diversion inspector came to</p>

<p style="text-align: right;">Page 732</p> <p>1 Janssen and inspected the system, the 2 suspicious order monitoring system, and had 3 concerns about that program, you're not 4 telling me that they would just do nothing, 5 right?</p> <p>6 MR. FULLER: Object to form. 7 Same Touhy issue.</p> <p>8 A. I can't answer that because of 9 the Touhy issue but I'm not making a comment 10 one way or the other on that statement.</p> <p>11 Taking the Touhy doesn't mean 12 that I'm not answering affirmatively or 13 negatively.</p> <p>14 BY MS. LUCAS:</p> <p>15 Q. Whether a suspicious order 16 monitoring program is compliant with the CSA 17 depends on the type of company and the scope 18 of the business model and customers you said 19 earlier, correct?</p> <p>20 A. Some of the things, yes, ma'am.</p> <p>21 Q. Would it also depend on the 22 medications at issue? Yes or no?</p> <p>23 A. That could have a bearing also.</p> <p>24 Q. The abuse rates of those 25 medications?</p>	<p style="text-align: right;">Page 734</p> <p>1 A. No, I do not at this time.</p> <p>2 Q. Do you know how many orders per 3 month Janssen received from its customers for 4 Nucynta?</p> <p>5 A. No, I do not, not at this time.</p> <p>6 Q. Do you know Janssen's market 7 share for its opioid medications sold in the 8 Track 1 jurisdictions?</p> <p>9 A. No, I do not at this time.</p> <p>10 Q. Do you know the rates of 11 diversion for Duragesic or Nucynta in the 12 Track 1 jurisdictions?</p> <p>13 A. I'm not sure there's any 14 analysis or information available to give any 15 concise rate of diversion of any drug.</p> <p>16 Q. So is that a no?</p> <p>17 A. I think that's a no.</p> <p>18 Q. Do you know how many shipments 19 of Duragesic Janssen flagged through its 20 algorithm and investigated as potentially 21 suspicious?</p> <p>22 A. Janssen's never reported a 23 suspicious order to the DEA.</p> <p>24 Q. My question was different.</p> <p>25 A. Oh, I'm sorry. Misunderstood</p>
<p style="text-align: right;">Page 733</p> <p>1 A. Yes, or the nonabuse rates.</p> <p>2 Q. The geographic location or 3 where they're being sold?</p> <p>4 A. Yes.</p> <p>5 Q. The sales volume in that 6 geography?</p> <p>7 A. That could be another factor, 8 yes, ma'am.</p> <p>9 Q. All right. I'm going to ask 10 you some quick yes or nos and then I need to 11 pass the witness while reserving my rights 12 since I have many, many more questions for 13 you.</p> <p>14 Do you know how many customers 15 Janssen had during the time it sold 16 Duragesic?</p> <p>17 A. No, I do not.</p> <p>18 Q. Do you know how many customers 19 Janssen had during the time it sold Nucynta?</p> <p>20 A. I have not evaluated that 21 information as far as the ARCOS, so, no, I do 22 not at this time.</p> <p>23 Q. Do you know how many orders per 24 month Janssen received from its customers for 25 Duragesic?</p>	<p style="text-align: right;">Page 735</p> <p>1 it then.</p> <p>2 Q. Do you know how many shipments 3 of Duragesic Janssen's algorithm flagged and 4 Janssen subsequently investigated before 5 releasing?</p> <p>6 A. I do not.</p> <p>7 Q. Do you know how many shipments 8 of Nucynta Janssen flagged as potentially 9 suspicious and investigated before releasing?</p> <p>10 A. I didn't do that type of 11 analysis up to today on that, on the data in 12 regards to those products and that 13 registrant.</p> <p>14 Q. Yes or no, did you know that 15 Janssen has reported a physician to the DEA 16 based on a sales representative's tip?</p> <p>17 A. I have not reviewed a document 18 that had indicated that to me, no, ma'am.</p> <p>19 Q. Do you know of any instance in 20 the Track 1 jurisdictions of Duragesic being 21 diverted?</p> <p>22 A. At this time, no, ma'am.</p> <p>23 Q. Do you know of any instance in 24 the Track 1 jurisdictions of Nucynta being 25 diverted?</p>

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1 A. At this time, no, ma'am.
2 Q. Do you know how many
3 inspection -- or strike that.
4 Do you know how many regulatory
5 investigations Janssen -- strike that again.
6 Do you know how many DEA
7 regulatory investigations of Janssen
8 distribution centers were conducted during
9 the relevant time period in this case?
10 A. I do not because that
11 information would not be available to me.
12 Q. Are you aware, yes or no, that
13 the DEA conducted multiple regulatory
14 investigations of Janssen using at least 14
15 different DEA diversion investigators since
16 2008?
17 A. Were those regulatory
18 investigations that -- I'm sorry, with your
19 question --
20 Q. Were you aware of --
21 A. Could you answer --
22 Q. Well, let me --
23 A. Could you restate that for me?
24 Just whether it was inspections or regulatory
25 investigations, I just need clarification.

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1 Q. Were you aware that the DEA
2 conducted multiple regulatory investigations
3 of Janssen using at least 14 different DEA
4 diversion investigators since 2008?
5 A. No, I'm not aware of that, but
6 just for clarification purposes, I've been at
7 manufacturers where there were groups of
8 people, so the number, multiple, I would
9 acknowledge is more than one.
10 But when you say 14 people, to
11 go to a manufacturer, sometimes there are
12 large groups of people that go, so...
13 Q. Is that a no?
14 A. It's -- so I would answer that
15 with the information you provided me, I
16 wouldn't comment. I don't know one way or
17 the other.
18 Q. Were you aware of any
19 regulatory investigations of Janssen by the
20 DEA since 2008?
21 A. I don't have any direct
22 knowledge of any investigations, ma'am.
23 Q. Did you ask to see any
24 documents reflecting DEA regulatory
25 investigations of Janssen?

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1 A. In my request and my
2 formulation of the opinion, yes, ma'am.
3 Q. And no --
4 A. Any actions, any comments, any
5 contact with the DEA, I asked for those
6 things.
7 Q. When did you ask for that?
8 A. It was all part -- early on
9 when I first started formulating my opinion,
10 there was a -- I'm sure that was one of the
11 requested documents. And also at the state
12 level; state inspections, state adverse
13 actions, administrative actions, MOAs, any --
14 and any resulting enforcement action.
15 Q. Were you aware that DEA
16 diversion investigator Billy Lane told
17 Janssen that he likes coming to places like
18 this during a regulatory investigation of
19 Janssen that he conducted?
20 A. That doesn't surprise me.
21 There's some registrant locations I like to
22 go to.
23 Q. Were you aware that despite
24 multiple DEA regulatory investigations of
25 Janssen since 2008, the DEA never once

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1 concluded that Janssen was in violation of
2 the Controlled Substances Act?
3 A. I don't have any information to
4 make comment on that, ma'am.
5 Q. Is that a no?
6 A. I'm not aware, no.
7 Q. And it's also true that DEA has
8 never initiated an enforcement action against
9 Janssen for its suspicious order monitoring
10 program, correct?
11 A. Not that I'm aware of as I sit
12 here today.
13 MS. LUCAS: Okay. I'm going to
14 reserve our rights on your time. We
15 can go off the record. Thank you very
16 much, I appreciate it.
17 THE WITNESS: All right. Thank
18 you.
19 THE VIDEOGRAPHER: Going off
20 the record at 3:08 p.m.
21 (Recess taken, 3:08 p.m. to
22 3:13 p.m.)
23 THE VIDEOGRAPHER: Back on the
24 record at 3:13 p.m.
25 ///

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1 EXAMINATION
2 BY MS. ZOLNER:
3 Q. Good afternoon, Mr. Rafalski.
4 I just introduced myself to you, but my name
5 is Erica Zolner and I represent Allergan.
6 I'm going to be asking you some questions
7 today on behalf of my client, and again,
8 because of limited time, I would ask if my
9 question just asks for a yes-or-no answer,
10 you give me a yes or a no.
11 A. If it's possible, I'll do that.
12 And good afternoon.
13 Q. Good afternoon.
14 Are there any additional
15 opinions on Allergan since your report was
16 served on April 15th?
17 A. No, there is not.
18 Q. I ask you if you had Exhibit 16
19 in front of you, and I think you do. Could
20 you look at page 12 and 13 of your report.
21 That's the page-numbered version.
22 A. Okay. Thank you. I'm guessing
23 that since you didn't say 1.
24 Q. Right.
25 A. Okay.

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1 Q. Do you see at the bottom of
2 page 12, right after you cite
3 Masters Pharmaceutical, you wrote: Beyond
4 requiring that a distributor must employ some
5 suspicious order monitoring system, SOMS, the
6 federal regulations do not make explicit
7 exactly what algorithms the SOMS must use to
8 identify suspicious orders, or exactly what
9 due diligence efforts are required when
10 investigating an order after it is identified
11 as suspicious.
12 Did I read that correctly?
13 MR. FULLER: Object to form.
14 That's not what he wrote. He's
15 quoting something.
16 A. I think that's my assessment of
17 what's contained in Discovery Ruling No. 12.
18 BY MS. ZOLNER:
19 Q. Right, and that's your
20 assessment, that's your writing, correct?
21 A. I wrote it, but it's the
22 assessment of the Discovery Ruling No. 12.
23 Q. Understood.
24 So is it your understanding
25 that manufacturers are required to use a

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1 particular algorithm in their suspicious
2 order monitoring system?
3 A. No, I am not.
4 Q. Are manufacturers prohibited
5 from using any particular algorithm in their
6 suspicious order monitoring system?
7 A. Other than one that's not
8 effective to disclose suspicious orders, no,
9 they're not.
10 Q. Is an SOM system noncompliant
11 if it uses an algorithm that incorporates a
12 multiplier?
13 A. A multiplier of two or three, I
14 would say yes.
15 Q. Yes. What about some other
16 multiplier other than two or three?
17 A. I've never had a --
18 MR. FULLER: Form.
19 A. I've never had the opportunity
20 to evaluate a system, but I guess thinking
21 about some systems that use standard
22 deviations or a couple that I reviewed that
23 have the Tukey box, it doesn't set a firm
24 threshold but gives a range.
25 So I would have to say -- I

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1 would say there's probably a possibility that
2 there could be a plus or minus to a
3 threshold, but it just wouldn't be a two or
4 three multiplier. That's essentially what a
5 standard deviation or a Tukey box is.
6 BY MS. ZOLNER:
7 Q. In this case, how did you
8 evaluate whether a company set its multiplier
9 at the appropriate level?
10 A. Based on my experience.
11 Q. When discussing the Watson
12 Pharmaceuticals suspicious order monitoring
13 system, on page 157 of your report, you said
14 that orders from wholesalers, distributors,
15 and chain pharmacies were regularly allowed
16 at triple the historical average or more.
17 Do you recall that?
18 A. My report says that?
19 Q. Yes.
20 A. Okay. Let me see. Page 157?
21 Q. Correct.
22 (Document review.)
23 BY MS. ZOLNER:
24 Q. Did you write that or did
25 someone else write that, Mr. Rafalski?

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1 MR. FULLER: I'm still looking
2 for what you read from, Counsel.
3 MS. ZOLNER: It's footnote 739.
4 MR. FULLER: Oh, you're in a
5 footnote. Okay. Sorry.
6 MS. ZOLNER: No, it's above
7 footnote 739. I'm sorry, I was just
8 giving you an identifier.
9 A. It starts on the page before?
10 BY MS. ZOLNER:
11 Q. It's on page 157.
12 A. The multiplier?
13 Q. The sentence that I just read
14 that includes "orders from wholesalers,
15 distributors and chain pharmacies were
16 regularly allowed at triple the historical
17 average or more" is right before you cite to
18 footnote 739.
19 Did you write that?
20 A. Yes, I did.
21 Q. What did you mean by regularly
22 in that sentence?
23 MR. FULLER: Maybe I'm just an
24 idiot, but I'm not seeing where she's
25 reading from. Are you seeing where

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1 she's reading from?
2 THE WITNESS: It starts right
3 here.
4 MS. ZOLNER: And I'm not going
5 to comment on what you said one way or
6 another, Mr. Fuller.
7 A. I'm not really sure right now.
8 BY MS. ZOLNER:
9 Q. You don't know what you meant
10 by regularly in that sentence?
11 A. I know what the sentence means,
12 but...
13 My recollection is that the
14 multiplier, when it was set by people in the
15 various trade -- various different trades,
16 there were -- there -- there were regular
17 occurrences where it allowed distributions
18 above the historical average, but that's my
19 recollection.
20 MS. ZOLNER: Move to strike as
21 nonresponsive.
22 BY MS. ZOLNER:
23 Q. What does regularly mean in
24 that sentence? And if you don't recall --
25 A. Often.

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1 Q. Often.
2 Do you know what multiplier
3 Watson Pharmaceuticals used for wholesalers
4 in 2004?
5 A. It's going to take me a minute
6 to review my report because of Allergan,
7 Watson, Actavis --
8 Q. Allergan.
9 A. Allergan.
10 Q. Right.
11 A. The three companies I want to
12 make sure I answer correctly.
13 Q. I understand, but again, we
14 have very limited time and there are
15 additional questioners waiting in the wings.
16 So do you know if you cited to
17 that in your report as you sit here today?
18 A. I believe I did.
19 Q. You think that you included the
20 multiplier that Watson Pharmaceuticals used
21 for wholesalers in 2004?
22 A. Oh, no, I believe I made a
23 comment or their system. I don't know if I
24 quoted. That's why I want to read it on
25 whether there was a multiplier.

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1 Q. We can take a break and go off
2 the record if you want time to familiarize
3 yourself with your report.
4 MR. FULLER: He's not going to
5 do that. He'll do it on the report.
6 MS. ZOLNER: Counsel,
7 Mr. Rafalski has taken an
8 extraordinary amount of time reviewing
9 his report and giving long answers to
10 questions that only require a yes or a
11 no.
12 Again, we're trying to be
13 efficient and we're trying to handle
14 this deposition in as -- as efficient
15 of a manner as possible, but to the
16 extent that he needs to look at his
17 report in order to answer these
18 questions and tell me if he included
19 certain facts in his report, we should
20 go off the record to allow him time to
21 review what he says he wrote himself.
22 MR. FULLER: No, ma'am.
23 MS. ZOLNER: Okay. Well, then
24 let the record reflect that Mr. Fuller
25 is refusing to allow Mr. Rafalski to

<p style="text-align: right;">Page 748</p> <p>1 go off the record, and if you could</p> <p>2 please mark the deposition with the</p> <p>3 time he's taken to review his report</p> <p>4 now.</p> <p>5 A. So my answer is contained in</p> <p>6 that similar section, but it's at the</p> <p>7 beginning.</p> <p>8 BY MS. ZOLNER:</p> <p>9 Q. Okay.</p> <p>10 A. I believe my review of the</p> <p>11 records indicate that there's a multiplier</p> <p>12 table and it's -- there's a variance</p> <p>13 dependent on -- it's set by people and it's</p> <p>14 not a firm multiplier.</p> <p>15 Q. Okay. I think you're talking</p> <p>16 about the multiplier data table that you cite</p> <p>17 in your report. Let's look at that document.</p> <p>18 A. The one -- yes.</p> <p>19 Q. It's what you cited to in</p> <p>20 footnote 739?</p> <p>21 A. I'm aware of the document.</p> <p>22 Q. Okay. So we're going to mark</p> <p>23 this --</p> <p>24 A. It has a three and a six</p> <p>25 multiplier.</p>	<p style="text-align: right;">Page 750</p> <p>1 at 1131, is this, to your knowledge, a slide</p> <p>2 with a computer screenshot?</p> <p>3 A. Or a re-creation of one.</p> <p>4 Q. Do you know what this</p> <p>5 screenshot shows?</p> <p>6 (Document review.)</p> <p>7 BY MS. ZOLNER:</p> <p>8 Q. Again, Mr. Rafalski, you cited</p> <p>9 to this in your report.</p> <p>10 A. Yes, I just need a second to</p> <p>11 review it.</p> <p>12 Q. Sure.</p> <p>13 A. I think it's stated below,</p> <p>14 tables used to calculate the values</p> <p>15 displayed.</p> <p>16 Q. Mr. Rafalski, I think you're</p> <p>17 looking at the wrong page.</p> <p>18 A. And it provides -- I'm sorry.</p> <p>19 Q. No, that's all right. I'm just</p> <p>20 looking over your shoulder -- or across the</p> <p>21 table by your shoulder, and it looks like</p> <p>22 you're on the wrong page. So it's 1131.</p> <p>23 A. I'm sorry. It shows the</p> <p>24 multiplier for SOMS and OMS.</p> <p>25 Q. It shows a multiplier for SOMS</p>
<p style="text-align: right;">Page 749</p> <p>1 MS. ZOLNER: We need to mark it</p> <p>2 as an exhibit.</p> <p>3 (Whereupon, Deposition Exhibit</p> <p>4 Rafalski-28, Actavis SOM Logic</p> <p>5 Presentation, ALLERGAN_MDL_02181128 -</p> <p>6 ALLERGAN_MDL_02181172, was marked for</p> <p>7 identification.)</p> <p>8 BY MS. ZOLNER:</p> <p>9 Q. If you could turn to page 1131.</p> <p>10 Those are the last four Bates numbers. This</p> <p>11 is the document you cited, correct,</p> <p>12 Mr. Rafalski?</p> <p>13 A. It is.</p> <p>14 Q. What's the date of this</p> <p>15 document?</p> <p>16 A. I don't see a date.</p> <p>17 Q. Is this the only document that</p> <p>18 you cite in your report that includes</p> <p>19 multipliers that Watson Pharmaceuticals used</p> <p>20 in its suspicious order monitoring system?</p> <p>21 A. I believe it is, yes, ma'am.</p> <p>22 Q. I believe you just told me you</p> <p>23 don't know the date of the document. This</p> <p>24 document that we're looking at right now, or</p> <p>25 the specific page we're looking at right now</p>	<p style="text-align: right;">Page 751</p> <p>1 and OMS, but where did you find this</p> <p>2 particular document?</p> <p>3 A. I know I reviewed it.</p> <p>4 Q. How did you come to review it?</p> <p>5 MR. FULLER: Counsel, maybe I</p> <p>6 don't understand. Are you asking</p> <p>7 where he obtained the document?</p> <p>8 A. I believe it's an exhibit to</p> <p>9 one of the depositions.</p> <p>10 BY MS. ZOLNER:</p> <p>11 Q. And you found this -- it's your</p> <p>12 testimony that you found this document</p> <p>13 attached as an exhibit to a deposition?</p> <p>14 A. That's my recollection right</p> <p>15 now, yes, ma'am.</p> <p>16 Q. Did you do any additional</p> <p>17 research into the background on this</p> <p>18 screenshot?</p> <p>19 A. I don't recall at this time,</p> <p>20 no, ma'am.</p> <p>21 Q. Did you do anything to</p> <p>22 determine the date of when the screenshot was</p> <p>23 captured?</p> <p>24 A. No, ma'am, I don't recall doing</p> <p>25 that either.</p>

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1 Q. Do you know whether the
2 multipliers in the screenshot were ever put
3 into effect?
4 A. I don't have recollection if
5 they were or not, no, ma'am.
6 Q. Do you know what entity this
7 screenshot is tied to?
8 A. Entity?
9 Q. Sure.
10 A. You mean which company?
11 Q. Correct.
12 A. Doesn't -- it doesn't say on
13 this other than Actavis down in the
14 right-hand corner.
15 Q. Did you do anything to
16 determine what entity this screenshot came
17 from?
18 A. No, ma'am.
19 Q. Do you -- do you know when the
20 multipliers in this screenshot were put into
21 effect, if at all?
22 A. I don't have any recollection
23 right now, no, ma'am.
24 Q. Do you know how long the
25 multipliers in this screenshot were in place?

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1 A. At this time, I don't have any
2 recollection, no, ma'am.
3 Q. Do you know whether the
4 multipliers in this screenshot were ever used
5 at all?
6 A. I'd like to look up a document.
7 One second, please.
8 Q. What document are you looking
9 for, Mr. Rafalski?
10 A. MDL02578082.
11 Q. Again, Mr. Rafalski, we do not
12 have time to look for documents right now.
13 I'm just going to ask you as
14 you sit here today, do you have any
15 recollection as to whether you have done any
16 investigation into whether these multipliers
17 were ever changed?
18 A. Independent of not letting me
19 look at this document, no, ma'am.
20 Q. You can look at the document on
21 a break, and if your testimony changes,
22 please let me know.
23 MR. FULLER: Counsel won't let
24 the witness finish his investigation.
25 MS. ZOLNER: Mr. Fuller, I

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1 suggested that if he does come upon
2 additional information, he can let me
3 know if his answer changes.
4 MR. FULLER: No, ma'am.
5 BY MS. ZOLNER:
6 Q. In your report --
7 MS. ZOLNER: No, he can't let
8 me know if his answer changes?
9 MR. FULLER: I'm not going to
10 have him go look at a document on a
11 break that you won't provide to him.
12 MS. ZOLNER: That's your
13 choice. That's your choice. I don't
14 need to argue with you on the record.
15 BY MS. ZOLNER:
16 Q. In your report, you claim you
17 considered all discovery responses of
18 defendants included in your report, correct?
19 A. Yes, ma'am.
20 Q. Did you review Allergan's
21 Responses to Plaintiffs' Fourth Set of
22 Interrogatories from February 25th, 2019?
23 A. Yes, ma'am.
24 Q. Do you recall that those listed
25 the multipliers that were used over time?

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1 A. I don't recall that.
2 Q. You don't recall reviewing
3 that?
4 A. I recall reviewing it. I don't
5 recall if I saw that information in the
6 responses.
7 Q. Would your opinion be affected
8 if the multipliers used by Watson were not
9 used as you described them in your report?
10 A. If my report is inaccurate,
11 yes, it would change my opinion.
12 Q. In your report on page 158 and
13 159, I think that's just a couple of pages
14 away. Let me know when you're there,
15 page 158.
16 A. I'm there.
17 Q. You say: The automated portion
18 of the system did not utilize any downstream
19 customer information available, did not
20 differentiate among NDC codes for drugs with
21 a higher risk of diversion, and only manually
22 stopped orders from shipping.
23 Do you see that?
24 A. You're on 158 or 159?
25 Q. It starts at the bottom of 158

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1 and goes to the top of 159.
2 A. Yes, I believe my review of the
3 system -- or that comment is referenced to
4 all occurred pre-2012.
5 Q. Okay. So does that statement
6 apply to pre-merger Watson?
7 A. No, ma'am.
8 Q. You said at the beginning of
9 page 159: Like the pre-merger Actavis
10 system.
11 Are you referring to another
12 entity other than pre-merger Watson?
13 A. I don't think so, no, ma'am.
14 Q. What entity are you referring
15 to?
16 A. Well, I think the merger was in
17 2012, so...
18 Q. So you are referring to
19 pre-merger Watson?
20 A. Well, the statement says that I
21 am, yes, ma'am.
22 Q. So it's your opinion that
23 pre-merger Watson only manually stopped
24 orders from shipping, correct?
25 (Document review.)

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1 BY MS. ZOLNER:
2 Q. Could I ask what you're looking
3 at, Mr. Rafalski? I know it's your report
4 but --
5 A. I'm just rereading -- rereading
6 a section. I make the statement that only
7 manually stopped orders from shipping.
8 Q. Right.
9 A. That's my recollection.
10 Q. So does that statement apply to
11 post-merger Actavis?
12 A. It would the way it's written,
13 yes, ma'am.
14 Q. You talk in your report about
15 pre- and post-merger entities. Do you know
16 the difference between the pre- and
17 post-merger entities?
18 A. I do.
19 Q. So is it your opinion that
20 post-merger Actavis only manually stopped
21 orders from shipping?
22 A. I'm not sure.
23 Q. You're not sure?
24 Do you know the difference
25 between the systems that pre-merger Actavis

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1 and post-merger Actavis used?
2 A. I think pre they had a
3 threshold based only related to the size,
4 pre-acquisition, Watson acquisition. Post, I
5 think it continued for a little bit and then
6 it rolled into the Watson system.
7 Q. How do you know that?
8 A. From reviewing the records
9 and -- that's my recollection.
10 Q. So what do you mean when you
11 say post, it continued for a little bit and
12 then it rolled into the Watson system?
13 A. It's just my recollection. Let
14 me review my report, but --
15 Q. Again --
16 A. It converted over into the
17 Watson system. That's just my recollection
18 of doing my opinion.
19 Q. I understand. And we have
20 limited time, so my question was specific to
21 whether post-merger Actavis was specifically
22 manually stopping orders. That was a couple
23 of questions ago, and I believe you said you
24 didn't know.
25 Did you -- so let me just see

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1 if I can reframe this and see if I can
2 refresh your recollection.
3 Did you review the deposition
4 transcript of Mary Woods in your preparation
5 of your report?
6 A. I did.
7 Q. Who is Mary Woods?
8 A. I don't have a recollection
9 right now. Although I say that I also
10 reviewed that last night.
11 Q. You reviewed Mary Woods'
12 transcript last night?
13 A. I did.
14 Q. So it should be fresh in your
15 memory. Do you recall who she worked for?
16 A. I believe Allergan --
17 Q. Allergan.
18 A. Sorry I keep mispronouncing it.
19 Q. Do you recall that she was the
20 corporate representative who testified about
21 pre-merger Watson and post-merger Actavis?
22 A. I don't have a direct
23 recollection of that.
24 Q. Okay. But you did review the
25 transcript last night?

<p style="text-align: right;">Page 760</p> <p>1 A. I did.</p> <p>2 Q. Do you recall reading from</p> <p>3 Ms. Woods' transcript that when it came to</p> <p>4 how the Watson system would pend orders, the</p> <p>5 system would automatically hold it?</p> <p>6 A. I don't have an independent</p> <p>7 recollection of that.</p> <p>8 Q. You don't recall if you read</p> <p>9 that last night?</p> <p>10 A. I may have read it. I just</p> <p>11 don't recall it.</p> <p>12 Q. Did you read that transcript in</p> <p>13 its entirety?</p> <p>14 MR. FULLER: You mean last</p> <p>15 night or ever?</p> <p>16 MS. ZOLNER: If he needs</p> <p>17 clarification he would ask. I would</p> <p>18 ask for you to quit coaching the</p> <p>19 witness.</p> <p>20 MR. FULLER: Object to form,</p> <p>21 vague.</p> <p>22 A. I read some last night, some</p> <p>23 this morning. I believe I read it in its</p> <p>24 entirety, although I tried to read it quicker</p> <p>25 than I normally would, and I read it previous</p>	<p style="text-align: right;">Page 762</p> <p>1 believe that Watson -- the Watson system only</p> <p>2 manually held orders given my representation</p> <p>3 to you that Mary Woods testified otherwise?</p> <p>4 A. No, I do not.</p> <p>5 Q. On page 158 of your report, you</p> <p>6 acknowledge that when Watson bought Actavis,</p> <p>7 the combined company used the Watson system,</p> <p>8 correct?</p> <p>9 A. To save time, you want to tell</p> <p>10 me --</p> <p>11 Q. Sure. I'm right after</p> <p>12 footnote 754 in the body of the text: But</p> <p>13 the new system was never implemented and when</p> <p>14 Watson bought Actavis, the combined company</p> <p>15 reverted to the Watson system until 2015 when</p> <p>16 it announced it was selling all of its</p> <p>17 generic drugs and various corporate</p> <p>18 subsidiaries to Teva, and as Napoli said,</p> <p>19 Teva already had their own program in place</p> <p>20 for suspicious order monitoring.</p> <p>21 A. Yes.</p> <p>22 Q. So that's written directly in</p> <p>23 your report.</p> <p>24 A. Yes.</p> <p>25 Q. Given that, why do you claim</p>
<p style="text-align: right;">Page 761</p> <p>1 to last night.</p> <p>2 I read it because of the -- the</p> <p>3 acquisitions and the changes and the multiple</p> <p>4 systems. It's a pretty complicated opinion,</p> <p>5 and I was trying to ensure that I would be</p> <p>6 prepared to answer these type of questions.</p> <p>7 And the -- this is a more complicated</p> <p>8 situation than the individual companies.</p> <p>9 BY MS. ZOLNER:</p> <p>10 Q. What do you mean by it's a</p> <p>11 pretty complicated opinion?</p> <p>12 A. Well, not opinion. A</p> <p>13 complicated review, because of the company</p> <p>14 acquisitions, the use of multiple systems or</p> <p>15 the overlap of systems. One system replaced</p> <p>16 another system.</p> <p>17 This was a difficult -- to keep</p> <p>18 all of it -- to be able to respond quickly to</p> <p>19 your questions, to keep all of that in</p> <p>20 sequence, it's --</p> <p>21 Q. Did you read this testimony</p> <p>22 before you wrote your report?</p> <p>23 A. Yes, and I also went back to</p> <p>24 certain specific footnotes also.</p> <p>25 Q. Do you have any basis to</p>	<p style="text-align: right;">Page 763</p> <p>1 that the combined company only manually</p> <p>2 stopped orders?</p> <p>3 A. I don't recall.</p> <p>4 Q. You don't recall why you make</p> <p>5 that assertion?</p> <p>6 A. Not at this time, no, ma'am.</p> <p>7 Q. As you sit here today, can you</p> <p>8 identify a single document that you reviewed</p> <p>9 that supports the assertion that Watson</p> <p>10 pre-merger only manually stopped orders?</p> <p>11 A. No, ma'am.</p> <p>12 Q. If a customer places an order</p> <p>13 and then decides to reduce it, does that</p> <p>14 always indicate diversion? It's a yes or no.</p> <p>15 A. When you use the term "always,"</p> <p>16 I would answer no.</p> <p>17 Q. If a customer places an order</p> <p>18 and then decides to cancel it, does that</p> <p>19 always indicate diversion?</p> <p>20 MR. FULLER: Let the record</p> <p>21 reflect counsel cut the witness off</p> <p>22 and he did not complete his answer.</p> <p>23 MS. ZOLNER: It's a yes-or-no</p> <p>24 question and I'm running out of time.</p> <p>25 A. I can't either answer yes or no</p>

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1 because there would -- in reviewing this, if
2 it's in response to a triggered order, a
3 suspicious order, and a customer would be
4 contacted, and there's a request to reduce it
5 based on the size and they agree to do that,
6 to fail -- to stop the triggering of a
7 suspicious order, then it would be a yes.
8 Does a registrant -- does any
9 person ordering a controlled substance have
10 the right to change their order? Yes, within
11 the regulations they could call and say
12 either cancel my order or reduce my order.
13 That's allowed, permissible under
14 regulations.
15 BY MS. ZOLNER:
16 Q. So your answer to my question
17 would be, no, if a customer places an order
18 and then decides to cancel it, it does not
19 always indicate diversion?
20 A. My -- my answer would be under
21 certain circumstances the answer would be
22 they could do that.
23 MS. ZOLNER: Could we take a
24 quick break? I need -- just need to
25 confer with my colleagues on a couple

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1 of issues.
2 THE VIDEOGRAPHER: Going off
3 the record, 3:40 p.m.
4 (Recess taken, 3:40 p.m. to
5 3:47 p.m.)
6 THE VIDEOGRAPHER: We're back
7 on the record at 3:47 p.m.
8 BY MS. ZOLNER:
9 Q. Mr. Rafalski, before the break
10 we were talking about reducing and canceling
11 orders. And we've talked a lot about
12 Allergan and pre-merger and post-merger
13 entities, but I want to talk specifically
14 right now about Watson and Watson's SOM
15 policy.
16 Would your opinion on
17 whether -- actually, let's turn to page 157
18 of your report. In Section 13 --
19 A. Yes.
20 Q. -- the first sentence says:
21 The Watson system affirmatively allowed
22 customers to get around violations by
23 canceling the order or cutting the quantity.
24 Do you see that?
25 A. I do.

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1 Q. And you say this policy was
2 consistent through 2012, a couple of lines
3 down, and you cite to footnote 742.
4 Do you see that?
5 A. Yes.
6 Q. Would your opinion be affected
7 if you found out that even before 2002 [sic],
8 Watson actually required customers to provide
9 legitimate reasons to reduce or cancel
10 orders?
11 A. So in regards to that, there
12 was -- I reviewed multiple policies that were
13 during this time period. There was Watson
14 policies that I reviewed.
15 I have a recollection that in
16 that policy I think a statement similar to
17 what you said appeared, but also contained
18 within those policies, also directed
19 employees the availability to either cut or
20 cancel an order, to terminate a suspicious
21 order.
22 MS. ZOLNER: Move to strike as
23 nonresponsive.
24 BY MS. ZOLNER:
25 Q. Would your opinion be affected

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1 if you found out that even before 2012,
2 Watson actually required customers to provide
3 legitimate reasons for canceling or reducing
4 orders? It's a yes or no.
5 MR. FULLER: Object to form,
6 incomplete hypothetical.
7 A. I'm not aware that that
8 occurred, but if that was something that I
9 missed or is available to me, I would
10 consider it in my opinion. I'm not sure
11 depending on how it would be written in the
12 context of it, but I would definitely look at
13 it and consider it in regards to my opinion.
14 BY MS. ZOLNER:
15 Q. Would it make a difference to
16 you?
17 A. As I stated --
18 MR. FULLER: Objection, asked
19 and answered.
20 A. -- it would depend on the --
21 just that comment, it would depend on the
22 totality of the document I reviewed and the
23 context of it or how it would be stated.
24 It's -- it's possible, yes.
25 ///

<p style="text-align: right;">Page 768</p> <p>1 BY MS. ZOLNER: 2 Q. So as you're sitting here right 3 now, you're leaving open the possibility that 4 it might not make a difference to you whether 5 Watson required customers to provide 6 legitimate reasons for canceling or reducing 7 orders? 8 MR. FULLER: Same objection. 9 A. So if that statement appeared 10 along in conjunction with first telling them 11 that their order had triggered a suspicious 12 order and just as hypothetical, so if there 13 was some -- it appeared within a policy or a 14 statement that was combined with the ability 15 to cut or transfer to circumvent a suspicious 16 order and then also have them provide a 17 reason why, I think there's the possibility 18 that -- that's why I answered the question 19 that way. There is a possibility that it 20 would not influence my opinion. I hope that 21 answers your question. 22 BY MS. ZOLNER: 23 Q. Do you know of any particular 24 order that Watson allowed to be reduced or 25 canceled without a legitimate reason?</p>	<p style="text-align: right;">Page 770</p> <p>1 A. No, I did not review specific 2 orders to see if I could determine by the 3 order whether or not it had been reduced or 4 terminated. 5 Q. How do you establish a pattern 6 for understanding how a company investigates 7 orders without looking at the orders 8 themselves? 9 MR. FULLER: Object to form. 10 A. Well, I -- I'm not saying that. 11 I'm saying in response to your question, for 12 me to be able to make a determination on a 13 terminated or cut order. I thought your 14 question was whether I looked at records to 15 determine if -- 16 BY MS. ZOLNER: 17 Q. That's right, Mr. Rafalski. I 18 asked you a question about whether you looked 19 at any specific orders, and you told me no. 20 As you sit here today, you 21 cannot identify a single order where Watson 22 allowed an order to be reduced or canceled 23 without the customer supplying a legitimate 24 business reason, correct? 25 A. I didn't see any records where</p>
<p style="text-align: right;">Page 769</p> <p>1 A. No, I do not. 2 MR. FULLER: Object to form. 3 A. But in reviewing the policies, 4 just allowing them to do that in regards to 5 terminating a suspicious order, whether they 6 did it or not, just the policy to have that 7 in place would make it an ineffective 8 suspicious order system. 9 BY MS. ZOLNER: 10 Q. Did you understand my question 11 that I asked you? Because I can repeat it. 12 A. No, maybe not if I -- 13 Q. Okay. My question was a very 14 simple one: Can you identify a single order 15 where Watson allowed -- do you know of any 16 particular order that Watson allowed to be 17 reduced or canceled without a legitimate 18 reason? 19 A. Not as I sit here today. I 20 have not reviewed the data for that 21 particular situation. 22 Q. So you did not review the data 23 to find out if Watson allowed for orders to 24 be reduced or canceled without a legitimate 25 reason?</p>	<p style="text-align: right;">Page 771</p> <p>1 that occurred, so I -- the answer -- 2 Q. So I'm correct? 3 A. Yes. 4 Q. So my question is: How do you 5 establish a pattern for understanding how a 6 company investigates orders without ever 7 looking at specific orders? 8 MR. FULLER: Object to form. 9 A. I look at -- I don't look at 10 specific orders. I look at the due diligence 11 records and what the registrant did. Just 12 looking at a specific order itself doesn't 13 provide me with that sufficient information. 14 BY MS. ZOLNER: 15 Q. Would your opinion be affected 16 if you found out that Watson actually 17 reported customers to the DEA if they tried 18 to cancel orders without any justification? 19 A. Would those be orders that were 20 identified as suspicious orders? 21 Q. My question is a simple one. 22 MR. FULLER: And he's just 23 asking for a complete hypothetical. 24 BY MS. ZOLNER: 25 Q. And I'll repeat it. Would your</p>

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1 opinion be affected if you found out that
2 Watson actually reported customers to the DEA
3 if they tried to cancel orders without
4 providing a justification?
5 A. Depending on the time frame and
6 the amount of orders and if it was a
7 consistent conduct by Watson, there's a
8 possibility that would be a yes, it would
9 affect my opinion.
10 Q. I'm still on page 157 of your
11 report, and again, if you're looking
12 around -- right before footnote 746, you
13 point out that from 2009 to 2011 the number
14 of SOMS validations at Watson increased, but
15 the number of administrators did not.
16 Do you see that?
17 A. Yes, I do.
18 Q. Do you know how many
19 administrators Watson had on staff to handle
20 SOMS validations between 2009 and 2012?
21 A. I don't have a direct
22 recollection of that.
23 Q. Do you have a general
24 recollection?
25 A. No.

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1 Q. Do you know whether the
2 administrators' other job responsibilities
3 changed in any way?
4 A. I don't have a recollection of
5 that at this time.
6 Q. Do you know whether Watson's
7 number of customers increased in that time?
8 A. I do not.
9 Q. Do you know if they decreased
10 in that time?
11 A. I do not.
12 Q. Do you know whether Watson
13 brought on any new customers during that
14 time?
15 A. I do not.
16 Q. Do you know whether any new
17 customers were purchasing controlled
18 substances at that time?
19 A. I didn't see any records that
20 would give me any guidance on that particular
21 issue, so I do not.
22 Q. So as you sit here today, do
23 you have any basis to conclude that the
24 administrators' duties were performed any
25 differently from 2009 to 2012?

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1 A. I think based on my review or
2 the review of the deposition, I make this
3 statement that there was an increase in the
4 average of SOMS that were assigned.
5 Q. Your review of the deposition.
6 What deposition are you referring to?
7 A. I think it was Ms. Woods'
8 deposition, I believe.
9 Q. And what specifically from
10 Ms. Woods' deposition are you using as your
11 basis to conclude that the administrators'
12 duties were performed any differently from
13 2009 to 2012?
14 A. I didn't say they were
15 performed differently. I just said that
16 there was an increase in the number of SOM
17 validations that were assigned to them.
18 Q. And I'm asking you a different
19 question, which is whether there's any reason
20 for you to conclude that the duties were
21 performed any differently from 2009 to 2012.
22 It's a yes or no.
23 A. No.
24 MS. ZOLNER: Mr. Rafalski, I
25 thank you very much for your time.

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1 Like all of my colleagues that
2 have gone before me, I just have to
3 say for the record that there are 86
4 Allergan and Actavis documents that
5 you cite in your report and in your
6 reliance materials. I obviously
7 haven't had time to question you on
8 most, the majority, practically all of
9 those documents, so I reserve all
10 rights to seek additional time from
11 the Court to continue to question you
12 about your opinions as they relate to
13 Allergan. But thank you again.
14 THE WITNESS: All right, thank
15 you. I hope we do this again.
16 MS. ZOLNER: I hope we meet
17 again, thanks.
18 THE VIDEOGRAPHER: Going off
19 the record at 3:56 p.m.
20 (Recess taken, 3:56 p.m. to
21 3:57 p.m.)
22 THE VIDEOGRAPHER: Back on the
23 record at 3:57 p.m.
24 ///
25 ///

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1 EXAMINATION
2 BY MR. SNAPP:
3 Q. Mr. Rafalski, we met off the
4 record. I'm Erik Snapp. I represent Purdue.
5 A. Good afternoon, sir.
6 Q. First of all, how much did you
7 spend on your Purdue section of your report
8 that starts on page 167 of Exhibit 16?
9 A. I don't have a recollection of
10 the exact amount of time.
11 Q. How about a ballpark? Was it
12 more than five hours?
13 A. I believe so, yes.
14 Q. More than ten hours?
15 A. I'm not exactly sure. I
16 believe it probably would be more than
17 10 hours.
18 Q. Okay. More than 50 hours?
19 A. No, sir.
20 Q. All right. More than 20 hours?
21 A. I'm not sure.
22 Q. All right. Did you review all
23 the documents and the transcripts that are
24 cited both in this section of the report from
25 pages 167 through 172 and that were included

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1 in your Schedule I, in terms of Purdue
2 documents?
3 A. I'm not sure in the volume that
4 you've described if I've looked at every
5 document. I'm confident that I looked at the
6 documents related to my report.
7 And then in regards to the
8 depositions, I'm not sure I completely read
9 them. May have read the areas that I've
10 cited or the pages before and after the parts
11 I cited, but I'm not sure that I read the
12 entire document --
13 Q. Fair enough.
14 A. -- deposition.
15 Q. You only cite from two
16 depositions. One is Frank Geraci, the rough
17 transcript, and that's footnotes 820 and 822
18 through 824, and then you cite to one of
19 Mr. Seid's depositions; is that right?
20 A. Yes, sir.
21 Q. You didn't review any other
22 depositions, correct?
23 A. No, sir, I don't believe so. I
24 don't have a recollection of doing that.
25 Q. And you didn't search for any

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1 documents as part of your work in this case
2 that would disprove your conclusions with
3 regard to any of the defendants you opined on
4 in your report, correct?
5 A. I just would search for
6 documents. If -- not what they're -- whether
7 they would prove or disprove my opinion. I
8 would look for documents to help me formulate
9 my opinion. I didn't -- I wasn't biased to
10 look for only certain documents.
11 Q. Once you reached your
12 conclusions, did you search for documents to
13 make sure that those conclusions were valid?
14 In other words, did you search for documents
15 that might disprove that conclusion?
16 A. I did not continue searching.
17 Q. So once you reached your
18 conclusions based on the documents you had
19 reviewed, you stopped searching for
20 additional documents; is that fair?
21 A. I've continued to look at
22 documents and continued -- you know, in my
23 efforts to -- because it's millions and
24 millions of documents, so I just didn't put
25 my report down and do nothing.

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1 I don't recall if I looked at
2 Purdue, but I've continued to look at
3 documents since I've submitted my report on
4 April 15th.
5 Q. Well, have you looked at any
6 additional Purdue documents since April 15th?
7 A. I don't recall if some of those
8 were Purdue or not.
9 Q. If you look at page 172, the
10 last paragraph of your section on Purdue, in
11 the middle of the paragraph there's a
12 sentence that reads: Purdue failed to use
13 consistent algorithms and failed to
14 investigate the suspicious orders identified
15 by the algorithms.
16 Do you see that?
17 A. Yes.
18 Q. Is it your testimony today that
19 Purdue failed to investigate all suspicious
20 orders that were identified by the
21 algorithms?
22 A. No, it's not. I believe there
23 was some due diligence conducted by the
24 company.
25 Q. So is that a mistake in your

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1 report?
 2 A. I say they conducted no due
 3 diligence in my report?
 4 Q. Well, you say they failed to
 5 investigate the suspicious orders identified
 6 by the algorithms. It doesn't say some
 7 suspicious orders. It says "the" suspicious
 8 orders identified by the algorithms.
 9 A. I believe that's not a general
 10 statement, but I think the documents I
 11 reviewed would say that that happened on a
 12 consistent basis.
 13 I'm not saying that there might
 14 have been due diligence for a customer or two
 15 in -- related to the files. That's my
 16 recollection.
 17 Q. Just for a customer or two,
 18 that's all?
 19 A. Well, I don't know, one or two,
 20 but there was some due diligence done by the
 21 company. It's not -- if that statement to
 22 you implies that none occurred, then that
 23 wouldn't be accurate because I know there was
 24 some due diligence.
 25 Q. You also didn't include any

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1 documents in your report with respect to
 2 Purdue's efforts to conduct site visits of
 3 pharmacies, right?
 4 A. I did not.
 5 Q. And you didn't read the
 6 December 12th, 2018 corporate representative
 7 deposition of Purdue, did you?
 8 A. The name of the representative?
 9 Q. His name was Stephen Seid. He
 10 was deposed as a fact witness and you cited
 11 his fact witness testimony?
 12 A. I believe --
 13 Q. But you didn't actually review
 14 his corporate representative deposition, did
 15 you?
 16 A. I don't believe so. I --
 17 Q. He was designated as a witness
 18 to testify on identification of Purdue's
 19 policies and procedures for and the
 20 identities of persons responsible for
 21 monitoring suspicious orders --
 22 A. Can I --
 23 Q. -- for potential diversion of
 24 opioids or opioid products.
 25 Were you aware of that

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1 testimony?
 2 A. Yes, and I misstated. I do
 3 recall. I don't know that I read the entire
 4 one, but I know I read the sections that I've
 5 cited in my report.
 6 Q. You didn't cite any sections of
 7 that deposition in your report, sir.
 8 A. I believe 815, is that not it?
 9 Q. No, it's a different
 10 deposition, sir.
 11 A. Fact deposition?
 12 Q. That was a fact deposition. He
 13 was deposed as the corporate representative
 14 of Purdue. He was speaking as the company.
 15 A. Then I misspoke.
 16 Q. So if a corporate
 17 representative was being offered to testify
 18 for the company with respect to the company's
 19 special [sic] order monitoring system, isn't
 20 that something that you would ask for?
 21 A. I would hope it would be
 22 provided to me.
 23 Q. You would hope that plaintiffs'
 24 lawyers would provide that testimony to you
 25 because it would be important for your

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1 understanding of Purdue's special order
 2 monitoring system to read that testimony,
 3 correct?
 4 MR. FULLER: Form.
 5 A. I'm not saying they didn't
 6 provide it to me. I may have it. I might
 7 not have reviewed it.
 8 BY MR. SNAPP:
 9 Q. Well, it wasn't cited in your
 10 report.
 11 A. I agree, so that means I didn't
 12 read it.
 13 Q. If you had read that -- well,
 14 first of all, you also, I assume, then,
 15 didn't review the exhibits to that
 16 deposition, correct, unless they were
 17 included otherwise in the documents that
 18 plaintiffs' counsel provided to you?
 19 A. If they were just -- if they
 20 were just attached to the deposition, then I
 21 probably would not have reviewed them. If
 22 they were exhibits that were also provided in
 23 discovery outside of the deposition, I may
 24 have cited them.
 25 Q. So I can tell you that the one

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1 I'm going to ask you about, you -- if you had
 2 reviewed the exhibits to that deposition, to
 3 the corporate representative deposition, sir,
 4 you would know that Purdue met with the DEA
 5 in April 2009 and provided an overview of its
 6 order monitoring system.
 7 You didn't know that, did you?
 8 It's not mentioned anywhere in your report, I
 9 can tell you that. Is that true?
 10 A. If it's not in my report, then
 11 I wasn't aware of it.
 12 Q. And if you'd read those
 13 exhibits, you also would have known that
 14 Purdue met again with the DEA in April 2011
 15 and provided an overview of its updated order
 16 monitoring system after its OxyContin
 17 reformulation, but you didn't know that
 18 either, did you?
 19 A. I didn't know they met, but --
 20 Q. Okay.
 21 A. -- if the suspicious order
 22 monitoring system they described was
 23 contained in other documents and it's
 24 referenced in my report, then...
 25 Q. You also didn't read Mr. Seid's

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1 testimony --
 2 MR. FULLER: Let him finish his
 3 answer. He wasn't done, Counsel. He
 4 can finish his answer.
 5 MR. SNAPP: Were you done, sir?
 6 THE WITNESS: Could you read
 7 back my answer for me, please?
 8 Because I was interrupted, I'm --
 9 MR. SNAPP: I'm sorry, it
 10 seemed like a natural break in your
 11 testimony so I just continued on,
 12 because I have limited time.
 13 MR. FULLER: We all do.
 14 (The following portion of the
 15 record was read.)
 16 "ANSWER: I didn't know they
 17 met, but if the suspicious order
 18 monitoring system they described was
 19 contained in other documents and it's
 20 referenced in my report, then..."
 21 (End of readback.)
 22 BY MR. SNAPP:
 23 Q. Then what?
 24 A. Then my opinion would be the
 25 same, if that is already included in my

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1 review.
 2 Q. Okay. But you also didn't read
 3 Mr. Seid's testimony or Mr. Crowley's
 4 testimony, for that matter, that no one at
 5 the DEA ever expressed any critique or
 6 complaint about Purdue's suspicious order
 7 monitoring system, correct?
 8 A. I don't have a recollection of
 9 reviewing either of those statements, no,
 10 sir.
 11 Q. So the DEA never told Purdue
 12 that it needed to change its system, but in
 13 your report here, you have concluded, based
 14 on somewhere between 10 and 50 hours of work
 15 and review of a handful of documents and two
 16 deposition transcripts, that Purdue's order
 17 monitoring system was inadequate, correct?
 18 A. I think based on their policies
 19 and their actions, I think I could come to
 20 that opinion, yes, sir.
 21 Q. Sir, would it ever be
 22 appropriate for a DEA employee to use his or
 23 her personal e-mail system to communicate
 24 with a registrant about the registrant's
 25 suspicious order monitoring system?

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1 MR. FULLER: Object to form.
 2 And as it applies to any internal DEA
 3 policies, you're not authorized to
 4 discuss it.
 5 THE WITNESS: I guess if that
 6 would be covered by my Touhy letter,
 7 if it's a DEA policy or procedures not
 8 available to the public, I --
 9 BY MR. SNAPP:
 10 Q. Well, generally speaking, in
 11 today's world, would it ever be appropriate
 12 for a government employee to use their
 13 personal e-mail for government business?
 14 MR. FULLER: We know it
 15 happens.
 16 A. Just a personal statement on
 17 that, not --
 18 BY MR. SNAPP:
 19 Q. What's your view? What's your
 20 view, sir?
 21 A. I think -- I think there were
 22 periods of time where that wasn't an issue or
 23 it wasn't stated whether or not that was a
 24 problem, and I think there were certain
 25 situations where it almost was required

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1 because of -- I'm trying to answer this
2 without causing a Touhy issue.
3 Q. I'll strike the question, sir.
4 A. Okay.
5 Q. Did you ever use your personal
6 e-mail account to communicate with a
7 registrant in your capacity as a DEA
8 employee?
9 A. I probably did early in my
10 career. I'm aware that I used -- I don't
11 recall this until I reviewed the document,
12 that I sent an e-mail to Jack Crowley.
13 Q. You did. You sent --
14 A. A couple.
15 Q. -- an e-mail to Jack Crowley
16 who was at Purdue, correct?
17 A. Yeah, I sent it to him and I
18 think I told him it was my personal e-mail
19 and I think I explained a reason why, but...
20 Q. Well, you didn't give a reason
21 why, but you did explain that it was your
22 personal e-mail.
23 So why did you send Mr. Crowley
24 an e-mail from your personal e-mail account
25 in 2009?

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1 A. I think I was tasked to contact
2 him, and I was involved in some kind of
3 project, and I either forgot or I didn't do
4 it, and I felt obligated to. So when I got
5 home that evening, I sent him an e-mail.
6 I didn't have -- at that period
7 of time I didn't have access to send a
8 government e-mail, unlike today, after hours,
9 after I left.
10 Q. So Mr. Crowley had contacted
11 you -- first of all, he was a Purdue
12 employee, right?
13 A. Yes.
14 Q. He headed up Purdue's
15 Controlled Substances Act compliance program?
16 A. At the time of that -- I know
17 that today, but at the time I made that
18 contact, I was asked by someone to give him
19 some guidance and given his information.
20 Q. Well, you were asked by him,
21 right?
22 A. No.
23 Q. You weren't?
24 A. Well, I wasn't asked by him to
25 contact him. I was told -- I was asked by

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1 someone else to contact him.
2 Q. So he didn't send you an e-mail
3 asking for your comments about his outline
4 with respect to making visits on pharmacies?
5 A. Yes, but the initial contact --
6 I don't believe he was given my e-mail. I
7 don't have a direct recollection. I can --
8 if you allow me to look at those documents.
9 Q. You didn't look at the
10 documents before opining about Purdue's
11 compliance program, right?
12 A. Those documents?
13 Q. Any of the documents related to
14 your communications with Mr. Crowley.
15 A. I've looked at those documents,
16 yes, sir.
17 Q. You didn't include them in your
18 report. So is it fair to say you're not
19 going to be testifying at trial about your
20 interactions with Purdue?
21 MR. FULLER: Object to form.
22 A. If those letters aren't
23 included in my report, I won't be talking
24 about those letters.
25 MR. SNAPP: Can we go off the

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1 record?
2 THE VIDEOGRAPHER: Off the
3 record at 4:10 p.m.
4 (Recess taken, 4:10 p.m. to
5 4:12 p.m.)
6 THE VIDEOGRAPHER: Back on the
7 record at 4:12 p.m.
8 BY MR. SNAPP:
9 Q. Sir, you know that Mr. Crowley
10 was planning to do some site visits of
11 pharmacies in 2009, correct, based on your
12 review of the documents?
13 A. Yes, sir. You're discussing in
14 regards to the e-mail communication?
15 Q. Yes, sir. And he contacted
16 you, he sent you an outline of questions he
17 intended to ask and his outline for those
18 site visits, correct?
19 A. I don't recall that.
20 Q. Well, you think -- you agree
21 that it was a good thing that Mr. Crowley was
22 incorporating site visits, pharmacy site
23 visits into the suspicious order monitoring
24 system at Purdue, correct?
25 A. Without reviewing the document,

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1 I know there was a communication, and I knew
 2 it was -- it's in regards to a visit to
 3 Detroit, and subsequent to those e-mails, I
 4 met him in person for a brief period of time.
 5 I don't think he did the site
 6 visits, based on my conversation when he was
 7 in Detroit, but -- so I -- I don't know
 8 without reading those documents.
 9 Q. You provided feedback to his --
 10 on his outline though, right?
 11 A. Yes, I was asked to answer some
 12 questions or give some guidance because he
 13 was coming to Detroit. And that's -- I
 14 recall that, but I don't recall an outline or
 15 any specific questions.
 16 Q. Okay. Well, I'm sure your
 17 counsel will show those to you before you
 18 testify at trial, sir, but let me ask you.
 19 What algorithms did Purdue use
 20 to identify potentially suspicious orders?
 21 You didn't discuss that in your report, did
 22 you?
 23 A. I believe I discussed the
 24 components, but I don't believe I put the
 25 specific algorithm in the report. That's my

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1 recollection.
 2 Q. Well, did the algorithms change
 3 over time, sir, in Purdue's system?
 4 A. I don't recall.
 5 Q. Sir, is it fair to say that
 6 you're not offering any opinions in this case
 7 that Purdue ever shipped an order that it
 8 should not have shipped?
 9 A. I think if I make the opinion
 10 that they had a failure to maintain effective
 11 controls to prevent diversion, and they had
 12 ineffective suspicious order systems, I think
 13 I'm making that opinion that they shouldn't
 14 have shipped the orders they shipped.
 15 Q. You're not offering any
 16 opinions in this case that Purdue ever
 17 shipped any particular order to Cuyahoga
 18 County or Summit County that it should not
 19 have shipped, are you?
 20 A. I'm not giving an opinion on a
 21 specific order.
 22 MR. SNAPP: Thank you. We can
 23 go off the record.
 24 THE VIDEOGRAPHER: Going off
 25 the record at 4:14 p.m.

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1 (Recess taken, 4:14 p.m. to
 2 4:17 p.m.)
 3 MR. SNAPP: I'm just going to
 4 make a statement for the record that
 5 Purdue reserves its rights to continue
 6 Mr. Rafalski's deposition in the same
 7 way that all the other defendants have
 8 made a reservation of rights, for the
 9 same reasons. Thanks.
 10 THE VIDEOGRAPHER: Back on the
 11 record at 4:18 p.m.
 12 EXAMINATION
 13 BY MR. FAUVRE:
 14 Q. Mr. Rafalski, my name is David
 15 Fauvre. I'm counsel for Endo and Par in this
 16 litigation.
 17 A. Okay.
 18 Q. And I'm going to be asking you
 19 questions about your report and the section
 20 that you -- of your report regarding Endo and
 21 Par is on pages 172 to 178.
 22 You also refer in your report
 23 to another entity named Qualitest, and I'll
 24 try to refer to those three entities as I'm
 25 asking you questions as we go.

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1 How much time did you spend
 2 writing this section on Endo, Par and
 3 Qualitest?
 4 A. I'm going to look at the
 5 length. It's hard for me to just give you an
 6 arbitrary number.
 7 Q. Six pages.
 8 A. 10 or 15 hours, maybe up to 20,
 9 approximately.
 10 Q. And did plaintiffs' counsel
 11 send you any sentences with citations that
 12 you used in the section regarding Endo, Par
 13 and Qualitest?
 14 A. I think it's a possibility
 15 there are some sentences here that were
 16 provided to me. Obviously I reviewed them
 17 and they're in my report, but there may be
 18 some sentences or some references in
 19 footnotes that I utilized, yes, sir.
 20 Q. And what about any whole
 21 paragraphs that they drafted that you made
 22 your own?
 23 A. I don't believe so, sir. I
 24 don't think there's anything here that's not
 25 been either edited or changed or drafted.

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1 Q. And you testified earlier that
2 the documents that you reviewed are the
3 documents that are either cited in your
4 report or cited in Schedule I of your report;
5 is that correct?

6 A. I think that's an accurate
7 statement.

8 Q. And those documents were
9 provided to you by plaintiffs' counsel based
10 on your request to them for particular
11 categories of documents?

12 A. Yes, and their assistance in
13 them looking for those type of documents.

14 Q. And did you request SOPs,
15 standard operating procedures, as part of
16 that request to plaintiffs' counsel?

17 A. That was one of the original
18 requests, yes.

19 Q. And if you did not include any
20 SOPs from either Endo, Qualitest or Par in
21 your report, would that be because you did
22 not review those SOPs as part of your
23 analysis?

24 MR. FULLER: Object to form.

25 A. I think that could be an

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1 accurate statement or the SOP wasn't relative
2 to my opinion, but generally speaking, if I
3 didn't cite it, it didn't have an influence
4 either one way or the other on my opinion.
5 Or I missed it, but...

6 BY MR. FAUVRE:

7 Q. And so SOPs related to either
8 of these companies' suspicious order
9 monitoring programs would not have been
10 relevant to this report; is that your
11 testimony?

12 MR. FULLER: Form.

13 A. No, that's not my testimony.

14 BY MR. FAUVRE:

15 Q. And so if there were SOPs
16 related to the suspicious order monitoring
17 program of any of these companies, you would
18 want to -- you want to have reviewed those;
19 is that correct?

20 A. Yes, and I hope I did.

21 Q. And if you didn't, would you
22 want to go back and review those to update
23 your report at some point?

24 A. If it changed my opinion, I
25 would do that, if it's not accurate.

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1 Q. And if there were other
2 presentations that the companies made, either
3 to DEA or internally, about their suspicious
4 order monitoring programs that you did not
5 include in either Schedule I or in your
6 report, would you want to go back and review
7 those to form your opinion for this report?

8 A. Information that was available
9 in the discovery?

10 Q. Yes.

11 A. Sure, if it would have an
12 influence that would change my opinion, I
13 would consider those documents. I would
14 consider anything that I missed that anyone
15 thought was relevant -- relevant to my
16 opinion because I want my opinion to be
17 accurate based on all of the available facts.

18 The problem I had in this --
19 not in just this instance, but it was the
20 volume of records make it virtually
21 impossible, I think 50 million documents.

22 Q. Sure. Understand.

23 And if you omitted certain
24 documents, is it possible that your report
25 might be missing some key elements of

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1 analysis?

2 A. If there's a record that I
3 didn't review or I missed, and it was
4 impactful upon my opinion, I would agree with
5 that statement.

6 I'm not aware that I -- I know
7 I did not intentionally omit documents to
8 formulate an opinion, but if it's something
9 that I did not see during my evaluation to
10 form my opinion, then I would obviously want
11 to know that.

12 Q. It's possible those documents
13 weren't provided to you based on your
14 requests of plaintiffs' counsel; is that
15 correct?

16 A. Well, I'm not sure I could
17 search 50 million documents, so I'm not going
18 to put that same expectation on someone else.

19 Q. Sure. But however the process
20 was, it's possible you missed documents that
21 could be relevant?

22 A. Yes, I think that's possible.

23 Q. You've talked a lot today and
24 in your report about the requirements of the
25 Controlled Substances Act and its

<p style="text-align: right;">Page 800</p> <p>1 implementing regulations?</p> <p>2 A. Yes.</p> <p>3 Q. Do those -- does that statute</p> <p>4 and the regulations apply to companies that</p> <p>5 do not register with the DEA?</p> <p>6 A. That's one of the interesting</p> <p>7 things that came up with Endo, because they</p> <p>8 don't hold a DEA registration, and that was a</p> <p>9 concern of mine when I was requested to</p> <p>10 provide an opinion.</p> <p>11 So in response to my question</p> <p>12 to the plaintiffs' attorneys, I was</p> <p>13 instructed that -- well, let me first state I</p> <p>14 reviewed records that brought to my attention</p> <p>15 they weren't a registrant when there was some</p> <p>16 agreements with -- and I don't remember</p> <p>17 exactly who they were. I think it was with</p> <p>18 the -- either stating they agreed with the</p> <p>19 government or it was a document that said</p> <p>20 they were telling the government that they</p> <p>21 were going to assume the responsibilities of</p> <p>22 a registrant; they're a virtual manufacturer.</p> <p>23 So first I did some research on</p> <p>24 a virtual manufacturer because that was new</p> <p>25 to me as a diversion investigator. So --</p>	<p style="text-align: right;">Page 802</p> <p>1 make for me in regards to that matter.</p> <p>2 But if a ruling came down it</p> <p>3 would make sense if they could not be treated</p> <p>4 as a registrant, I couldn't apply the -- I</p> <p>5 personally couldn't apply rules and</p> <p>6 regulations to them as a registrant.</p> <p>7 Q. And the standards you applied</p> <p>8 in coming up with your opinion in this report</p> <p>9 and what you intend to testify to at trial is</p> <p>10 based on an analysis of whether they complied</p> <p>11 with the Controlled Substances Act and the</p> <p>12 implementing regulations?</p> <p>13 A. That was the standards I</p> <p>14 applied, yes, sir.</p> <p>15 Q. In looking at Endo's program</p> <p>16 specifically, you reference on page 174 an</p> <p>17 algorithm in paragraph -- numbered</p> <p>18 paragraph 5 that says: The SOM program looks</p> <p>19 at buying wholesaler customers' 3-month and</p> <p>20 12-month history and if any order is above</p> <p>21 the 3- or 12-month, it goes on hold and it is</p> <p>22 reviewed by customer service.</p> <p>23 Is that correct?</p> <p>24 A. Yes, sir.</p> <p>25 Q. Is that the algorithm that you</p>
<p style="text-align: right;">Page 801</p> <p>1 this is a long story -- I mean, not long</p> <p>2 story.</p> <p>3 But so when I brought this</p> <p>4 situation up with the plaintiffs' attorneys,</p> <p>5 they told me that that was a legal matter and</p> <p>6 that was something that would be decided</p> <p>7 between the attorneys at a later date.</p> <p>8 So I treated my opinion as if</p> <p>9 they were a registrant.</p> <p>10 Q. So your opinion is based on the</p> <p>11 assumption that the Controlled Substances Act</p> <p>12 and its implementing regulations and the</p> <p>13 requirements to have a suspicious order</p> <p>14 monitoring program apply to nonregistrants?</p> <p>15 A. Yes, knowing that -- I informed</p> <p>16 the plaintiffs' attorneys about that and they</p> <p>17 were aware of that, yes, sir.</p> <p>18 Q. And if it turns out that those</p> <p>19 obligations do not apply to nonregistrants,</p> <p>20 then your opinion as it relates to Endo would</p> <p>21 not be accurate?</p> <p>22 MR. FULLER: Object to form.</p> <p>23 A. I don't know that I could draw</p> <p>24 a legal conclusion. I think that's some --</p> <p>25 something that someone at the court would</p>	<p style="text-align: right;">Page 803</p> <p>1 reviewed to come up with your opinion as to</p> <p>2 Endo's sufficiency under the Controlled</p> <p>3 Substances Act?</p> <p>4 A. I think the main concern on</p> <p>5 using just that to determine suspicious</p> <p>6 orders, it was an evaluation of only size,</p> <p>7 and it didn't consider frequency and pattern.</p> <p>8 Q. And then Endo later modified</p> <p>9 its algorithm to include size -- quantity,</p> <p>10 size and frequency? That's in your report in</p> <p>11 the next paragraph.</p> <p>12 A. Yes, yes, yes, 2014. But the</p> <p>13 opinion above was based on that --</p> <p>14 Q. So after 2014, do you believe</p> <p>15 that the algorithm that Endo employed was</p> <p>16 sufficient?</p> <p>17 MR. FULLER: Somebody that's on</p> <p>18 the phone, we can hear you. Can you</p> <p>19 make sure you're muted, please?</p> <p>20 Sorry.</p> <p>21 BY MR. FAUVRE:</p> <p>22 Q. Yes or no?</p> <p>23 A. No, I think there were other</p> <p>24 factors that weren't included in the SOM</p> <p>25 system I think they had access to.</p>

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1 Q. What about the algorithm, just
2 the algorithm itself as a way to flag
3 potentially suspicious orders, is that -- is
4 the system that they employed after 2014 a
5 sufficient system to flag potential
6 suspicious orders?
7 A. I think my concern is what they
8 compared it to, the 3- and 12-month average.
9 I mean, it's their own purchasing average,
10 but I'm not sure that there was a comparison
11 to, like, customers or just standing on its
12 own, a 3- and a 12-month algorithm was a
13 concern to me.
14 Q. Isn't that a more restrictive
15 analysis than Methodology A, which looks at
16 the highest month's total in the past six
17 months? Here they're looking at an average
18 over three months and over 12 months, which
19 necessarily would be below the highest month
20 in either of those periods.
21 A. It's definitely a layered
22 algorithm, so it looks at two different time
23 spans. The 3-month algorithm is too short of
24 a period for me to be impactful. The
25 12-month algorithm, using that as an average,

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1 if that's the threshold and there's no
2 multiplier, I think that's a good start to
3 identify a suspicious order.
4 Q. And are you aware that the FDA
5 approved that very methodology in the risk
6 map that Endo submitted for its Opana ER
7 product?
8 MR. FULLER: I'm sorry, FDA?
9 MR. FAUVRE: FDA.
10 A. I'm not aware of that.
11 BY MR. FAUVRE:
12 Q. Okay. Moving to Qualitest, you
13 identify in numbered paragraph 9, you say:
14 As late as March 2013, Qualitest's SOM
15 process had multiple deficiencies.
16 And then you list several.
17 Were those deficiencies
18 corrected after March 2011?
19 A. Well, later in there I report
20 some deficiencies in regards to the ability
21 to stop orders in different tiers.
22 Q. But the deficiencies you
23 identified in paragraph 9, those were
24 corrected after March 2013; is that correct?
25 A. I think Qualitest took steps to

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1 make changes. I'm not sure they fully
2 integrated -- my recollection is they didn't
3 fully integrate the chargeback. I think that
4 started to take a look at chargeback
5 information after 2013.
6 So I'm not sure I could make
7 a -- I would be in agreement that they
8 started to make changes, but I don't know
9 that they -- I would say they were fully
10 compliant based on the availability of some
11 other information they could have
12 incorporated.
13 Q. And is it your opinion that
14 Qualitest's SOMS program was deficient in
15 2014 or does your opinion stop in the 2013
16 period?
17 A. I don't give -- I don't give a
18 stopping date, but then I also don't make
19 comment on any changes that would be a system
20 that I thought was sufficient.
21 So I'm --
22 Q. Do you have an opinion as to
23 whether Qualitest's program was sufficient
24 after 2013, so from 2014 forward?
25 A. I don't make a statement in my

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1 report, but I believe it was because I don't
2 state otherwise.
3 Q. So do you plan to offer
4 testimony at trial that Qualitest's program
5 was insufficient from 2014 until the present?
6 A. I think I'll testify currently
7 to exactly what's in my report.
8 Q. Which is that it was
9 insufficient up until 2013 and then you take
10 no opinion from 2014 on?
11 A. Well, I think it says after the
12 spring of 2013, but it doesn't give a date up
13 to some of the -- some of the section of my
14 report give a date up to today or up to the
15 date of submission of my report.
16 I agree that this doesn't have
17 an ending date of my review. It just
18 concludes after the spring of 2013.
19 I believe my recollection is,
20 is that that statement, it continued on after
21 that date, but I would only testify to the
22 content of my report, if I was...
23 Q. And so the deficiencies you've
24 identified in your report existed in 2013,
25 but did not exist after 2013?

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<p>1 A. I'm not sure.</p> <p>2 Q. You take no opinion on whether</p> <p>3 the Qualitest SOMS program was sufficient in</p> <p>4 2014?</p> <p>5 A. I don't make -- well --</p> <p>6 Q. And --</p> <p>7 A. -- I'm concerned because I</p> <p>8 don't say that they were -- I would make</p> <p>9 comment. If there was a correction and I</p> <p>10 thought there was a proper or a compliant</p> <p>11 suspicious order system, I would make comment</p> <p>12 on that in my report.</p> <p>13 The failure to make that</p> <p>14 comment leads me to believe -- because I -- I</p> <p>15 would take a little bit of time just to</p> <p>16 review some documents, but I believe that it</p> <p>17 remained deficient based on the failure for</p> <p>18 me to say that it was corrected.</p> <p>19 Q. But you cite no evidence or</p> <p>20 support for the belief that it was deficient</p> <p>21 after 2014; is that correct?</p> <p>22 A. In my report, I do not.</p> <p>23 Q. And you don't intend to offer</p> <p>24 any testimony at trial that the program was</p> <p>25 deficient after 2014; is that correct?</p>	<p>1 time as well as the other defendants</p> <p>2 have to come back and question this</p> <p>3 witness. We have a lot more to cover.</p> <p>4 But thank you for your time.</p> <p>5 THE WITNESS: Okay. Thank you.</p> <p>6 THE VIDEOGRAPHER: Going off</p> <p>7 the record. The time is 4:34 p.m.</p> <p>8 (Recess taken, 4:34 p.m. to</p> <p>9 4:36 p.m.)</p> <p>10 THE VIDEOGRAPHER: We're back</p> <p>11 on the record at 4:36 p.m.</p> <p>12 EXAMINATION</p> <p>13 BY MS. BARBER:</p> <p>14 Q. Good afternoon, Mr. Rafalski.</p> <p>15 My name is Maureen Barber and I represent the</p> <p>16 Teva defendants. And these defendants are</p> <p>17 covered on pages 178 to 185 of your report.</p> <p>18 And I'll represent to you that</p> <p>19 these defendants consist of Teva, Cephalon</p> <p>20 and Actavis entities. Would you agree</p> <p>21 with that those pages of your report cover</p> <p>22 your opinions on those particular defendants?</p> <p>23 A. Yes, I do.</p> <p>24 Q. How much time did you spend</p> <p>25 reviewing documents related to your opinions</p>
Page 809	Page 811
<p>1 A. I think I would probably make</p> <p>2 the same statement that I made here today.</p> <p>3 Q. That you don't have an opinion</p> <p>4 one way or another as to the program after</p> <p>5 2014?</p> <p>6 A. No, that it would be my opinion</p> <p>7 that I would have -- if I thought that it was</p> <p>8 changed, I would give credit to Qualitest</p> <p>9 that it had a satisfactory suspicious order</p> <p>10 system, and by that not appearing here, I</p> <p>11 don't believe that's the case.</p> <p>12 Q. And you haven't identified</p> <p>13 anywhere in your report any suspicious orders</p> <p>14 that were allowed to ship by either</p> <p>15 Qualitest, Endo, or Par; is that correct?</p> <p>16 A. I have not, no individual</p> <p>17 orders have been identified up to this point</p> <p>18 of my report, no, sir.</p> <p>19 Q. And you have not identified any</p> <p>20 orders that were diverted that arose from</p> <p>21 suspicious orders from either Endo, Par or</p> <p>22 Qualitest; is that correct?</p> <p>23 A. No specific orders have been</p> <p>24 identified by this report.</p> <p>25 MR. FAUVRE: Okay. I reserve</p>	<p>1 for Cephalon, Teva and Actavis entities? Was</p> <p>2 it more than ten hours?</p> <p>3 A. I believe it was.</p> <p>4 Q. More than 20 hours?</p> <p>5 A. No, I don't think so.</p> <p>6 Q. So somewhere between 10 and</p> <p>7 20 hours?</p> <p>8 A. I believe so.</p> <p>9 Q. You mentioned in your report</p> <p>10 ValueCentric data in the Teva defendants</p> <p>11 section of your report.</p> <p>12 Would you agree?</p> <p>13 A. I do.</p> <p>14 Q. Are you familiar with</p> <p>15 ValueCentric data?</p> <p>16 A. I've reviewed records and I'm</p> <p>17 aware that as part of my evaluation, to give</p> <p>18 you a description and evaluation or a</p> <p>19 description, at this current time I'm not</p> <p>20 able to do that, but I have read it in parts</p> <p>21 of the deposition and other records.</p> <p>22 Q. Did you review any ValueCentric</p> <p>23 867 data in relation to your assessment of</p> <p>24 Teva's suspicious order monitoring system?</p> <p>25 A. I don't recall reviewing the</p>

<p style="text-align: right;">Page 812</p> <p>1 867 data.</p> <p>2 Q. Can you tell me what 867 data</p> <p>3 is, what the source of the data is? It's in</p> <p>4 your report, so you must have -- you must</p> <p>5 have an understanding of what 867 data is; is</p> <p>6 that correct?</p> <p>7 A. The term "867 data," and I</p> <p>8 believe I have a recollection, but it doesn't</p> <p>9 describe it, and I don't want to misstate.</p> <p>10 Q. But nonetheless, you think that</p> <p>11 it's important for Teva to have 867 data</p> <p>12 incorporated in its suspicious order</p> <p>13 monitoring program, but you don't know what</p> <p>14 ValueCentric 867 data is? Is that what</p> <p>15 you're telling us?</p> <p>16 A. I believe it was an internal</p> <p>17 system that did -- my recollection is it was</p> <p>18 an inventory type of a system that could look</p> <p>19 at distributions and on-hand inventory. And</p> <p>20 that's my recollection of what it was.</p> <p>21 Q. Okay. So you're not sure what</p> <p>22 that information would provide to Teva, the</p> <p>23 Teva defendants, for purposes of</p> <p>24 incorporating that information into their</p> <p>25 suspicious order monitoring system?</p>	<p style="text-align: right;">Page 814</p> <p>1 Q. We discussed that today?</p> <p>2 A. Yes.</p> <p>3 Q. In your report in the sections</p> <p>4 related to the Teva defendants, you don't</p> <p>5 offer any opinion about whether any of the</p> <p>6 Teva defendants should have used IMS or IQVIA</p> <p>7 data as part of their suspicious order</p> <p>8 monitoring systems, correct?</p> <p>9 A. I don't recall that they had</p> <p>10 availability to that data.</p> <p>11 Q. You testified earlier also</p> <p>12 about chargeback data and using chargeback</p> <p>13 data to detect suspicious orders.</p> <p>14 Do you remember that testimony</p> <p>15 today?</p> <p>16 A. I do.</p> <p>17 Q. Only certain contracts generate</p> <p>18 chargeback data, correct?</p> <p>19 A. Well, that's dependent on each</p> <p>20 manufacturer and dependent on which products</p> <p>21 they want to offer chargebacks.</p> <p>22 Q. Right. So you would agree with</p> <p>23 me that chargeback data would have limited</p> <p>24 utility in detecting suspicious orders if</p> <p>25 only a portion of a registrant's customers</p>
<p style="text-align: right;">Page 813</p> <p>1 A. Well, sure, because I think</p> <p>2 it -- if my recollection is correct, they</p> <p>3 would know -- when an order came in from a</p> <p>4 registrant, they would know how much product</p> <p>5 the registrant had on hand.</p> <p>6 Q. The Value- -- would you agree</p> <p>7 with me that the ValueCentric 867 data is</p> <p>8 dependent on the information that the</p> <p>9 customers provide to ValueCentric? Would you</p> <p>10 agree with that statement?</p> <p>11 A. Yes, it is.</p> <p>12 Q. And some customers might not</p> <p>13 provide any information to ValueCentric;</p> <p>14 wouldn't you agree?</p> <p>15 A. There is a possibility that</p> <p>16 some registrants might share the information,</p> <p>17 but I would hope that if a registrant would</p> <p>18 not share information that would help prevent</p> <p>19 diversion, that would be a consideration that</p> <p>20 a manufacturer or distributor would take into</p> <p>21 effect before they distribute controlled</p> <p>22 substances.</p> <p>23 Q. You also mentioned in your</p> <p>24 report IMS and IQVIA data; isn't that right?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 815</p> <p>1 had contracts that generated chargeback data;</p> <p>2 wouldn't you agree?</p> <p>3 A. No, I would not agree because</p> <p>4 on that particular controlled substance, it</p> <p>5 would provide additional relevant transaction</p> <p>6 data. So if it was a controlled substance --</p> <p>7 and I know my report focuses on opioids, but</p> <p>8 any controlled substance where you would be</p> <p>9 able to have that downstream information, I</p> <p>10 think it would be impactful on a suspicious</p> <p>11 order report.</p> <p>12 Q. Do you know what percentage of</p> <p>13 entities who received products from Teva</p> <p>14 purchased products through contracts that</p> <p>15 generate chargeback data?</p> <p>16 A. I don't recall that</p> <p>17 information.</p> <p>18 Q. So -- and you would also agree</p> <p>19 with me that downstream pharmacies or</p> <p>20 downstream registrants that purchase from</p> <p>21 wholesalers who are likely to redirect the</p> <p>22 product through illegitimate channels would</p> <p>23 not want to generate chargeback data.</p> <p>24 Wouldn't you agree with that?</p> <p>25 A. No, I would not agree with</p>

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1 that.
2 Q. So you're telling me that a
3 pharmacy who is likely to redirect the
4 product through illegitimate channels would
5 want to generate chargeback data?
6 A. Well, my experience in doing
7 these investigations is the chargeback is
8 kind of the amount of profit in a
9 transaction. So typically, if there was
10 no -- if a chargeback was available, it's
11 built into the price, and if you refuse to
12 accept the chargeback, that discount makes it
13 nonprofitable.
14 So typically, a registrant
15 would not handle a drug where a chargeback is
16 available.
17 Q. So a pharmacy who is --
18 A. It's possible, but that would
19 be my experience, that I have not come across
20 where a pharmacy would say I don't care about
21 the chargeback, I still want to make the
22 purchase from you.
23 Q. Right. So a pharmacy wouldn't
24 want to create a paper trail; isn't that
25 correct?

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1 A. No. What I'm saying is because
2 of the profit -- the income built into the
3 chargeback, I would say that they probably
4 wouldn't care about whether or not the
5 distributor knew about that.
6 Q. Did you review any chargeback
7 data for Cephalon?
8 A. I don't believe I did, no.
9 Q. How about for any of the
10 Actavis entities?
11 A. I don't recall that I reviewed
12 specific chargeback data.
13 Q. And speaking specifically about
14 Cephalon, you're aware that they manufactured
15 Actiq and Fentora and generic Actiq; isn't
16 that correct?
17 A. I believe that was brought to
18 my attention in reviewing records for this
19 report, yes, ma'am.
20 Q. You're not offering any
21 opinions about whether any of those products
22 were diverted, are you?
23 A. I'm offering an opinion about
24 the suspicious order system of the
25 registrants and it's not relative to any

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1 specific product.
2 Q. Are you offering any opinions
3 about whether any of those products were
4 improperly shipped?
5 A. I'm just going to restate.
6 It's whether or not there was an effective
7 suspicious order system in place. It's not
8 relative to any specific product. If a -- if
9 the manufacturer sold it and they had no
10 suspicious order in place, that would be the
11 opinion I would place, not whether or not --
12 the scenario you described.
13 Q. The DEA regulations, including
14 the Controlled Substances Act and the Code of
15 Federal Regulations, do not require that
16 registrants -- they don't state that
17 registrants must audit their own suspicious
18 order monitoring system; isn't that correct?
19 A. There's nothing directly which
20 tells them that. That would be a prudent and
21 advisable practice, but I don't think there's
22 nothing specifically that orders them to do
23 that.
24 Q. And there's nothing in either
25 of those regulations stating that a

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1 registrant has to retain a third-party
2 consultant to review their suspicious order
3 monitoring system?
4 A. No, absolutely not. The
5 requirement puts that burden of compliance
6 directly on the registrant.
7 Q. Where in the --
8 A. What steps they take, if they
9 were to go to a third-party consultant,
10 that's strictly at their free choosing.
11 Q. So it doesn't state that in the
12 regulations?
13 A. It does not require them to do
14 that or state they should ever do that. It
15 says they have to do that, not a third party.
16 Q. Mr. Rafalski, you reviewed a
17 report prepared by Mr. Buzzeo and his
18 consulting firm in conjunction with preparing
19 your report in this case, right?
20 A. I did.
21 Q. And Mr. Buzzeo and his
22 consulting firm was retained to review Teva's
23 suspicious order monitoring system in 2012,
24 correct?
25 A. They did -- they were, and my

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1 recollection is they did not implement their
 2 system.
 3 Q. What do you mean they didn't
 4 implement their system?
 5 A. Buzzeo was not retained as a
 6 consultant and the Buzzeo system was not
 7 implemented at the company.
 8 Q. And at that time, he was
 9 reviewing the Suspicious Orders I system for
 10 Teva, correct?
 11 A. I think that's an accurate
 12 statement, yes.
 13 Q. And at no point does the report
 14 conclude that Teva's suspicious order
 15 monitoring system was not compliant with DEA
 16 regulations; isn't that a correct statement?
 17 A. Say that again.
 18 Q. At no point in Mr. Buzzeo's
 19 report does he conclude that the Teva
 20 suspicious order monitoring system was not
 21 compliant with DEA regulations; wouldn't you
 22 agree?
 23 A. I think -- I think he was
 24 critical of the functionality of it, but in
 25 reading other reports by Mr. Buzzeo, I don't

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1 think he draws -- makes that conclusion. At
 2 least he doesn't put it in his reports,
 3 because he's not a DEA representative.
 4 Q. The DEA regulations don't state
 5 what type of suspicious order monitoring
 6 model a registrant has to use; isn't that
 7 correct?
 8 A. No, it's up to the registrant
 9 to design their system that meets their
 10 business needs and accomplishes the
 11 identification of suspicious orders.
 12 Q. And it doesn't state anything
 13 about what standard deviations or what number
 14 of standard deviations a registrant should
 15 use in its algorithm for monitoring
 16 suspicious orders?
 17 A. It does not give guidance in
 18 that area.
 19 Q. At the time the Buzzeo
 20 report -- I'm sorry, strike that.
 21 The Buzzeo report concluded
 22 that SORDS II, which is an improvement on the
 23 SORDS I suspicious order monitoring program,
 24 that Teva had in place was an improvement
 25 over SORDS I; isn't that correct?

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1 A. I believe he did make that
 2 comment, yes. He didn't say that it was
 3 sufficient to be compliant, but he did say it
 4 was an improvement.
 5 Q. But again, he didn't say that
 6 it wasn't compliant with DEA regulations?
 7 A. No, I didn't say that.
 8 Q. My question to you is: He
 9 didn't say that it wasn't compliant with DEA
 10 regulations?
 11 A. He never made that exact
 12 statement.
 13 Q. Teva also had an internal audit
 14 of its own suspicious order monitoring
 15 program?
 16 A. I believe so, yes.
 17 Q. And that program was rated
 18 overall as effective, correct?
 19 A. Yes, but it's an internal
 20 audit.
 21 Q. The DEA regulations don't
 22 require that companies actively audit their
 23 own programs, correct?
 24 A. No, that's true. But I only
 25 make that statement because sometimes the

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1 person that does the audit, without knowing
 2 the full information on the audit, is the
 3 person in charge of the system, so they don't
 4 typically give a bad audit to themselves.
 5 So, I mean, I'm not totally
 6 discounting it, but I'm always concerned
 7 about internal audits.
 8 Q. Mr. Rafalski, in your report
 9 you don't identify any suspicious order that
 10 Teva shipped to Summit County or Cuyahoga;
 11 isn't that correct?
 12 A. I do not identify any single
 13 suspicious order -- any order specifically
 14 that was suspicious.
 15 Q. And that goes for Cephalon and
 16 the Actavis entities as well, correct?
 17 A. As I sit here today, that's an
 18 accurate statement.
 19 Q. And you don't identify any
 20 order that Teva failed to flag as suspicious?
 21 A. Is that question a specific
 22 order?
 23 Q. Any order that Teva failed to
 24 flag as suspicious, you don't have an example
 25 of any specific order?

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1 A. No, I think my examples in here
2 are more -- go more to the conduct of the due
3 diligence and it doesn't specifically say
4 that there was a specific order, but I think
5 the totality of the incident that I describe
6 on page 183 I think would include that, but
7 to answer your question, there's no specific
8 order where I state that.

9 Q. And I want to ask you quickly
10 about that order.

11 You're speaking of the Publix
12 Supermarket pharmacies incident or scenario
13 that we discussed -- that's in your report on
14 page 183?

15 A. Yes, I am.

16 Q. The orders involving the Publix
17 Supermarket pharmacies were not orders placed
18 from Publix to Teva, were they?

19 A. No, they were placed to a
20 distributor, an in-between so --

21 Q. Right. They were orders placed
22 from Publix to Anda, correct?

23 A. Yes. But so the first concern
24 that I would have with this is that Teva
25 would need a means of effective controls to

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1 go to Anda and see why this situation
2 occurred.

3 Q. And it did do that, correct?

4 A. I don't recall that occurring.

5 Q. Well, so you read the
6 deposition of Joe Tomkiewicz, didn't you?

7 A. Yes.

8 Q. And sitting here today, you
9 don't know whether any of Teva's product was
10 ultimately shipped to one of those Publix
11 Supermarkets that Joe Tomkiewicz identified
12 as entities he wanted to look into, correct?

13 A. Based on my review, he was
14 looking at the chargebacks, and I believe
15 they were Teva products.

16 Q. But you would agree with me
17 that Joe Tomkiewicz testified he didn't see
18 any specific orders of Teva's products,
19 correct?

20 A. Yes, but if they weren't Teva's
21 products, I'm not sure that he would have
22 taken all this action unless he was
23 indicating it was someone else's product that
24 he was going to go investigate.

25 Q. Well, he could have been

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1 looking at those because Anda is his
2 customer, correct?

3 A. Yes.

4 Q. Right. And he was looking at
5 Publix's forecasting data, correct?

6 A. Yes.

7 MR. FULLER: Counsel, I believe
8 the 14 hours is up.

9 MS. BARBER: All right. At
10 this time I am going to reserve my
11 time. I haven't had -- along with my
12 colleagues, haven't had adequate time
13 to ask questions of Mr. Rafalski,
14 which is a violation of our clients'
15 due process, and we reserve any
16 additional time in the future to
17 examine Mr. Rafalski or reexamine
18 Mr. Rafalski.

19 MS. SWIFT: Before we break,
20 I'd like to put one additional thing
21 on the record.

22 Mr. Rafalski, you said your
23 method for assessing the defendants'
24 suspicious order monitoring system is
25 based on your experience, training and

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1 legal guidance from lawyers at the
2 DEA.

3 Just yes or no, does your Touhy
4 authorization --

5 MR. FULLER: Don't answer this
6 question.

7 MS. SWIFT: -- prevent you from
8 disclosing the legal guidance from DEA
9 lawyers that supports your opinion?

10 MR. FULLER: Don't answer the
11 question. She's over her time.

12 Off the record.

13 THE VIDEOGRAPHER: Going off
14 the record, 4:52 p.m.

15 (Recess taken, 4:52 p.m. to
16 4:52 p.m.)

17 (The following proceedings were
18 conducted off the videotaped record.)

19 MR. MATTHEWS: Good afternoon.
20 This is James Matthews. I represent
21 Anda Inc. I've sat here for two days
22 at this deposition and have not asked
23 any questions because the name Anda
24 doesn't appear in your report.

25 However, in the last series of

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<p>1 questions, for the first time in two 2 days, the name Anda came up in your 3 testimony. However, because of the 4 limits placed on the defendants for 5 asking questions at these depositions 6 and because we have exceeded those 7 limits at this point in time, I am not 8 able to ask you questions, and so for 9 the record, I want to put on the 10 record that we object to that 11 procedure and that we reserve our 12 rights to seek an opportunity to ask 13 you questions should you seek to offer 14 an opinion about Anda at trial. 15 Thank you very much. 16 MS. SWIFT: And I'll just add 17 that counsel instructed the witness 18 not to answer at 7 hours and one 19 minute. We were one minute over our 20 time and we were cut off. 21 THE REPORTER: Done? 22 MR. PYSER: Mr. Rafalski, can 23 you confirm that you're not going to 24 answer Ms. Swift's question? 25 MR. FULLER: Don't answer that.</p>	<p>1 A. Good afternoon, Mr. Fuller. 2 I'm fine, thank you. 3 Q. This is only going to take a 4 few minutes. 5 In your report on approximately 6 page 40 through 43, 44 identifies several 7 methodologies and the results that Mr. McCann 8 came up with based on those results, applying 9 them to the ARCOS data in the distributors' 10 own information, correct? 11 A. Yes, sir. 12 Q. And I want to make sure we're 13 clear, because there was some going back and 14 forth about that. 15 What you have put in your 16 report is the dosage units from those 17 results, correct? 18 MS. SWIFT: Objection, leading. 19 MR. FULLER: You can answer. 20 A. Yes, sir. 21 BY MR. FULLER: 22 Q. She's going to object; she's 23 just preserving her right for the record. 24 A. I understand. 25 Q. Okay. Underlying those dosage</p>
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<p>1 MR. PYSER: Based on the 2 instruction of counsel, are you going 3 to answer the question or not? 4 MR. FULLER: No, I'm going to 5 have a couple of minutes, so, 6 Mr. Pyser, if you want to ask him 7 after I get my couple of minutes in, 8 you can. 9 MR. MATTHEWS: If you're going 10 to have additional questions, I'd like 11 a -- 12 THE REPORTER: Are we still on 13 the record? I can't hear down at the 14 end of the table. I can't hear that. 15 We're off the record. 16 (Recess taken, 4:54 p.m. to 17 4:56 p.m.) 18 (Whereupon the videotaped 19 record resumes.) 20 THE VIDEOGRAPHER: We're back 21 on record, 4:56 p.m. 22 EXAMINATION 23 BY MR. FULLER: 24 Q. Good afternoon, Mr. Rafalski, 25 how are you?</p>	<p>1 units would be individual orders to 2 individual pharmacies within CT1; is that 3 your understanding? 4 MS. SWIFT: Objection, leading. 5 A. That's correct. Every dosage 6 unit that is listed here would be as the 7 result of an order to a registrant in CT1. 8 BY MR. FULLER: 9 Q. And of these five 10 methodologies, I think you opined earlier, 11 and correct me if I'm wrong, that the first 12 methodology, which was derived out of the 13 Masters case, was the one that you chose to 14 utilize as being appropriate as an initial 15 trigger, correct? 16 MS. SWIFT: Objection, leading. 17 A. I believe that was my -- 18 THE WITNESS: That's okay. I'm 19 sorry I interrupted you and didn't 20 wait. 21 A. Yes, that -- that was my 22 earlier testimony. 23 BY MR. FULLER: 24 Q. And just so the record is 25 clear, because everybody's referred to them</p>

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1 as different things, methodologies, SOMS.
 2 You're not saying that the methodology
 3 selected is a complete SOM system; it's only
 4 a system to give initial triggers for
 5 suspicious orders, correct?
 6 A. I think that was my previous
 7 testimony, but that would be the first part
 8 of a suspicious order system, to identify an
 9 order, in this case, only -- in size only.
 10 Q. And multiple counsel have asked
 11 you today related to -- or asked you
 12 questions related to your assumptions or your
 13 assumption -- excuse me -- your opinion that
 14 once a suspicious order is triggered, if due
 15 diligence isn't conducted, the failure to
 16 remove that due diligence means all the other
 17 orders are suspicious from that point
 18 forward?
 19 MS. SWIFT: Objection, vague.
 20 A. I believe I've stated that
 21 numerous times over the last two days.
 22 BY MR. FULLER:
 23 Q. And I believe you provided some
 24 of your bases, but you've also reviewed and
 25 read portions of Mr. Prevoznik's testimony as

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1 the 30(b) for the DEA in this litigation,
 2 right?
 3 A. I did read his section where he
 4 speaks to that same -- he doesn't speak to
 5 the methodology, but he speaks to the same
 6 position from the DEA.
 7 MR. FULLER: A.J., hand me my
 8 yellow expandable.
 9 So I'm going to hand you and
 10 mark as Exhibit -- what exhibit are we
 11 up to?
 12 (Whereupon, Deposition Exhibit
 13 Rafalski-29, Plaintiff Cardinal Health
 14 Inc.'s Reply in Support of Motion for
 15 Preliminary Injunction, was marked for
 16 identification.)
 17 BY MR. FULLER:
 18 Q. So Plaintiffs' Exhibit 29, have
 19 you seen this document before?
 20 A. I have.
 21 MS. SWIFT: Do you have a copy?
 22 BY MR. FULLER:
 23 Q. If you turn to page 17. And
 24 for the record, this is attached to
 25 Mr. Prevoznik's depo as either Exhibit 8 or

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1 9.
 2 Now, on page 17, it reads:
 3 Cardinal Health's policy -- and this is a
 4 pleading Cardinal filed in its action in the
 5 United States District Court for the District
 6 of Columbia against Eric Holder.
 7 It says: Cardinal Health's
 8 policy about which it informed the DEA as
 9 early as 2009 was that if a customer order
 10 could not be filled because it was
 11 suspicious, Cardinal Health would terminate
 12 controlled substance sales to the customer
 13 and report the termination to the DEA.
 14 Do you see that?
 15 A. Yes, sir, I do.
 16 Q. Is that consistent with your
 17 opinion that if you can't clear due
 18 diligence, you have to cut off the
 19 customer -- or excuse me.
 20 If you can't do -- if you don't
 21 do adequate due diligence to dispel the
 22 suspicion, that you have to cut off the
 23 customer or you can no longer ship controlled
 24 substances to them?
 25 MS. SWIFT: Objection,

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1 compound.
 2 A. I would also state that if you
 3 cut the order, there would be no requirement
 4 for a suspicious order under the Masters
 5 ruling. You could -- you could do due
 6 diligence, but if you identified an order and
 7 cut it, stopped any future shipment, I
 8 believe it wouldn't be necessary to do due
 9 diligence.
 10 BY MR. FULLER:
 11 Q. Meaning because you're not
 12 shipping to them again?
 13 A. Yes.
 14 Q. Okay. But if you receive a
 15 suspicious order and you do not dispel the
 16 suspicion, you can't continue to ship to that
 17 customer, correct?
 18 A. That's correct.
 19 (Whereupon, Deposition Exhibit
 20 Rafalski-30, 8/13/14 Rocque Letter to
 21 Hobart [MCKMDL Bates Obscured], was
 22 marked for identification.)
 23 BY MR. FULLER:
 24 Q. So Plaintiffs' Exhibit 30.
 25 Have you seen this document before?

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<p>1 A. I have.</p> <p>2 Q. And I'll represent to you that</p> <p>3 it's also attached to Mr. Prevoznik's</p> <p>4 deposition, and if you go to page 16. And</p> <p>5 this is related to McKesson.</p> <p>6 And in the middle of the</p> <p>7 paragraph under number 5, it says: As the</p> <p>8 manual explains, quote, once McKesson deems</p> <p>9 an order or -- and/or a customer suspicious,</p> <p>10 McKesson is required to act. This means that</p> <p>11 all controlled substance sales to that</p> <p>12 customer must -- customer must cease and the</p> <p>13 DEA must be notified.</p> <p>14 And that's consistent with your</p> <p>15 position as well, correct?</p> <p>16 MR. EPPICH: Objection,</p> <p>17 leading.</p> <p>18 A. Yes, sir.</p> <p>19 BY MR. FULLER:</p> <p>20 Q. These methodologies that you</p> <p>21 identified, 1 through 5, they could also be</p> <p>22 ran on the manufacturers' shipments to its</p> <p>23 customers, correct?</p> <p>24 MR. O'CONNOR: Objection, form.</p> <p>25 A. Yes, the methodologies could be</p>	<p>1 MR. O'CONNOR: Objection, form.</p> <p>2 MR. FULLER: I'm sorry, go</p> <p>3 ahead.</p> <p>4 A. Any relevant transactions.</p> <p>5 MR. FULLER: I don't have</p> <p>6 anything further.</p> <p>7 THE VIDEOGRAPHER: Going off</p> <p>8 the record, 5:04 p.m.</p> <p>9 (Recess taken, 5:04 p.m. to</p> <p>10 5:14 p.m.)</p> <p>11 THE VIDEOGRAPHER: We're back</p> <p>12 on the record at 5:14 p.m.</p> <p>13 EXAMINATION</p> <p>14 BY MR. MATTHEWS:</p> <p>15 Q. Good afternoon, Mr. Rafalski.</p> <p>16 I already introduced myself to you but just</p> <p>17 for the record, I'm James Matthews. I</p> <p>18 represent Anda Inc.</p> <p>19 A. Good afternoon.</p> <p>20 Q. How are you.</p> <p>21 I want to take you back to the</p> <p>22 beginning of the day. There were some</p> <p>23 questions asked of you by Ms. Swift who</p> <p>24 represented Walgreens.</p> <p>25 Do you remember that very</p>
Page 837	Page 839
<p>1 applied to any of the persons involved in the</p> <p>2 CT1 litigation.</p> <p>3 BY MR. FULLER:</p> <p>4 Q. And counsel's asked you several</p> <p>5 times about know your customer -- customer's</p> <p>6 customer.</p> <p>7 Do you recall that line of</p> <p>8 questioning?</p> <p>9 A. Yes, I do.</p> <p>10 Q. Is it your opinion that</p> <p>11 whatever information a registrant has,</p> <p>12 whether it be in the sales department or any</p> <p>13 other department within their organization,</p> <p>14 that if it would be valuable to use for the</p> <p>15 suspicious order monitoring system, it should</p> <p>16 be used for that purpose as well?</p> <p>17 MR. O'CONNOR: Objection, form.</p> <p>18 A. I agree and I believe I've</p> <p>19 testified to that on numerous occasions in</p> <p>20 the last two days.</p> <p>21 BY MR. FULLER:</p> <p>22 Q. And that's whether it's</p> <p>23 chargeback data, IQVIA data,</p> <p>24 doctor detailing data, pharmacy visits --</p> <p>25 A. Any relevant transaction --</p>	<p>1 beginning of the day, right in the morning?</p> <p>2 A. I recall I was interviewed or</p> <p>3 deposed about Walgreens. I don't</p> <p>4 specifically -- the questions, I don't</p> <p>5 recall.</p> <p>6 Q. Okay. You issued 183 --</p> <p>7 180-some-odd-page report, right?</p> <p>8 A. Yes, sir.</p> <p>9 Q. And in that, you set forth your</p> <p>10 opinions, and you told Ms. Swift that all of</p> <p>11 your opinions are in that report, right?</p> <p>12 A. Of the companies that I</p> <p>13 evaluated, the opinion -- of -- yes.</p> <p>14 Q. Yes.</p> <p>15 And the bases for those</p> <p>16 opinions, except insofar as they're based on</p> <p>17 your own personal experience and knowledge,</p> <p>18 are in the footnotes to that report, right?</p> <p>19 MR. FULLER: I'm going to</p> <p>20 object, and if I can have a running</p> <p>21 objection that this is outside my</p> <p>22 cross.</p> <p>23 MR. MATTHEWS: That's fine, you</p> <p>24 can have your objection, thank you.</p> <p>25 MR. FULLER: Thank you.</p>

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1 A. I think it's an accurate
2 statement. It was based on the review of the
3 records that I cited.
4 BY MR. MATTHEWS:
5 Q. Okay. There's not a single
6 document created by Anda Inc. cited in any of
7 the footnotes in your report, right?
8 A. That's correct.
9 Q. And that means that there's --
10 and there's no depositions of any Anda Inc.
11 employees cited in any of the footnotes of
12 your report, right?
13 A. There is not.
14 Q. In fact, you haven't done
15 anything to look at Anda's suspicious order
16 monitoring program, right?
17 A. I have not.
18 Q. And since there's no
19 information that would be the basis for any
20 opinions as to Anda's suspicious order
21 monitoring system in your report, it's safe
22 to say that there are no opinions about
23 Anda Inc. in your report, right?
24 A. There's no opinions of Anda in
25 the current report, right here, no, sir.

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1 Q. And so I'd like you, if you
2 could, to just open your report to page 7.
3 You know that Anda, Inc. is one of the
4 defendants in this action, right?
5 A. I believe so, yes, sir.
6 Q. Okay. Looking at page 7 of
7 your report, in the second full paragraph,
8 you wrote: I am of the opinion to a
9 reasonable degree of professional certainty
10 that there was a systematic, prolonged
11 failure over many years by the defendant
12 manufacturers and distributors to maintain
13 effective controls against diversion of
14 legitimate opioid prescriptions into the
15 illicit market.
16 Did I read that correctly?
17 A. You did.
18 Q. So Anda is a defendant, right?
19 A. Yes, sir.
20 Q. And that opinion as described
21 on page 7 does not apply to Anda, right?
22 A. As I sit here today, no, I have
23 not reviewed any records related to Anda.
24 Q. Okay. I want to ask one more
25 question following up on your testimony.

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1 During the course of the
2 deposition, you've said on several occasions
3 that your method for assessing the
4 defendants' suspicious order monitoring
5 systems is based in part on your experience,
6 training and guidance from lawyers at DEA; is
7 that correct?
8 Do you remember that testimony?
9 A. Yes, sir.
10 Q. Okay. This is just a yes-or-no
11 answer: Does the Touhy authorization that
12 you received for today's testimony prevent
13 you from disclosing the legal guidance from
14 DEA lawyers that supports your opinions?
15 A. So just so I understand the
16 question. Does the Touhy letter prevent me
17 from answering that question?
18 Q. Right.
19 A. I believe it does, yes.
20 MR. MATTHEWS: Thank you. I
21 have no further questions.
22 THE VIDEOGRAPHER: Going off
23 the record, 5:18 p.m.
24 (Proceedings recessed at
25 5:18 p.m.)

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1 CERTIFICATE
2 I, MICHAEL E. MILLER, Fellow of
3 the Academy of Professional Reporters,
4 Registered Diplomate Reporter, Certified
5 Realtime Reporter, Certified Court Reporter
6 and Notary Public, do hereby certify that
7 prior to the commencement of the examination,
8 JAMES E. RAFALSKI was duly sworn by me to
9 testify to the truth, the whole truth and
10 nothing but the truth.
11 I DO FURTHER CERTIFY that the
12 foregoing is a verbatim transcript of the
13 testimony as taken stenographically by and
14 before me at the time, place and on the date
15 hereinbefore set forth, to the best of my
16 ability.
17 I DO FURTHER CERTIFY that pursuant
18 to FRCP Rule 30, signature of the witness was
19 not requested by the witness or other party
20 before the conclusion of the deposition.
21 I DO FURTHER CERTIFY that I am
22 neither a relative nor employee nor attorney
23 nor counsel of any of the parties to this
24 action, and that I am neither a relative nor
25 employee of such attorney or counsel, and
that I am not financially interested in the
action.
MICHAEL E. MILLER, FAPR, RDR, CRR
Fellow of the Academy of Professional Reporters
NCRA Registered Diplomate Reporter
NCRA Certified Realtime Reporter
Certified Court Reporter
Notary Public
My Commission Expires: 7/9/2020
Dated: May 15, 2019

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

ACKNOWLEDGMENT OF DEPONENT

I, JAMES E. RAFALSKI, do hereby certify that I have read the foregoing pages and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

JAMES E. RAFALSKI DATE

Subscribed and sworn to before me this _____ day of _____, 20 _____.
My commission expires: _____

Notary Public

ERRATA

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